IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

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| MICHELLE MCMUNN, et al., Plaintiffs, vs BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants. | ) | Civil Action No. 10-143 |
| JESSI ANN CASELLA, et al., Plaintiffs, vs BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants. | ) | Civil Action No. 10-368 |
| MICHAEL P. HUTH, et al., Plaintiffs, vs BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants. | ) | Civil Action No. 10-650 |
| LINDA W. DILICK, Plaintiff, vs BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants. | ) | Civil Action No. 10-728 |
| BONNIE AIKENS, et al., Plaintiffs, vs BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al., Defendants. | ) | Civil Action No. 10-744 |
| PATRICIA ALTIMIRE, et al., Plaintiffs, vs | ) | Civil Action No. 10-908 |

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| BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al.,<br>Defendants. | ) | |
| HEATHER LORRAINE BAYNAR, et al.,<br>Plaintiffs,<br>vs | ) | Civil Action No. 10-1736 |
| BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al.,<br>Defendants. | ) | |
| MARCIA BAUSTERT, et al.,<br>Plaintiffs,<br>vs | ) | Civil Action No. 11-898 |
| BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al.,<br>Defendants. | ) | |
| SANDRA L. AMENT, et al.,<br>Plaintiffs,<br>vs | ) | Civil Action No. 11-1381 |
| BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al.,<br>Defendants. | ) | |
| ELIZABETH MITCHESON, et al.,<br>Plaintiffs,<br>vs | ) | Civil Action No. 12-1221 |
| BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al.,<br>Defendants. | ) | |
| KAREN L. SKROUPA,<br>Plaintiff,<br>vs | ) | Civil Action No. 12-1459 |
| BABCOCK & WILCOX POWER GENERATION GROUP, INC., et al.,<br>Defendants. | ) | |

I. Recommendation

It is respectfully recommended that Defendants' Motion to Exclude Expert Opinions of Mr. Bernd Franke and Joseph Ring, Ph.D., under *Daubert* be granted. It is further recommended that Defendants' Motion to Exclude Expert Testimony and Opinions of Donal Kirwan be denied. It is further recommended that Defendants' Motion to Exclude Expert Opinions of Howard Hu under *Daubert* be granted. It is further recommended that Defendants' Motion to Exclude Testimony of James Melius under *Daubert* be granted. It is further recommended that Plaintiffs' Motion to Exclude the Opinions of Defendant Babcock & Wilcox's Retained Expert John E. Till Ph.D. be denied. It is further recommended that Plaintiffs' Motion to Exclude the Opinions of Defendant Babcock & Wilcox's Retained Experts Dr. Christopher Whipple and Stanley Hayes be denied. It is further recommended that Plaintiffs' Motion to Exclude Testimony and Report of Fred A. Mettler, Jr., M.D., M.P.H. be denied. It is further recommended that Plaintiffs' Motion to Exclude Testimony and Studies of Dr. Boice be denied. It is further recommended that, if the Court adopts this Report and Recommendation, Plaintiffs be given 21 days from the date of the order to show cause why summary judgment should not be entered in Defendants' favor for the reasons stated herein.

II. Report

Plaintiffs bring the above-captioned actions alleging that Defendants, Babcock & Wilcox Power Generation Group, Inc., B&W Technical Services, Inc. (together, "B&W") and Atlantic Richfield Co., as successors in interest to the Nuclear Materials Corporation ("NUMEC"), are responsible for the release of radioactive, hazardous and toxic substances into the environment surrounding two nuclear materials processing facilities located in the Borough of Apollo and in Parks Township, Pennsylvania, during the operation, remediation and/or decommissioning of

these facilities. Plaintiffs (approximately 75 individuals who lived and/or worked in the area near the plants) allege that the releases have contaminated the air, soil, surface water and ground water in the surrounding communities and caused them personal injuries and property damages. Plaintiffs assert jurisdiction under the Price-Anderson Act, 42 U.S.C. § 2210(n)(2), and the Atomic Energy Act, 42 U.S.C. § 2011, and also assert state law claims of negligence, negligence per se, strict liability, civil conspiracy, and wrongful death and survival, for which supplemental jurisdiction is asserted pursuant to 28 U.S.C. § 1367(a). As a result of the discovery process, one facility (Parks) has been eliminated and only personal injuries that can be linked to inhalation of enriched uranium released from the Apollo facility during its period of operation are still at issue in these cases.

Currently pending before the Court are eight motions to exclude expert testimony, opinions and/or reports pursuant to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), four filed by Plaintiffs and four by Defendants. The motions have been fully briefed and a hearing was held on April 30 and May 1, 2013. For the reasons that follow, some of the motions should be granted and others should be denied. In addition, because the motions to exclude the testimony of Plaintiffs' general and specific causation experts should be granted, they should be directed to show cause why summary judgment should not be entered in Defendants' favor.

Procedural History

The first case, McMunn v. Babcock & Wilcox Power Generation Group, Inc., No. 10-143, was filed on January 29, 2010 and assigned to Judge Cercone. Subsequently, ten additional cases were filed and assigned to various district judges. The undersigned volunteered to conduct common discovery on these cases and a series of status conferences were held to set

discovery deadlines and resolve issues. On January 24, 2012, a Case Management Order was entered (ECF No. 109)[1], which required Plaintiffs to provide Defendants with admissible evidence establishing the prima facie elements of their individual claims. After this occurred, Defendants filed motions seeking to limit Plaintiffs' cases based upon the alleged failure to submit such evidence. Pursuant to an order entered on September 12, 2012 (ECF No. 161) and thereafter affirmed by all the district judges, the motions were granted in part and denied in part and Plaintiffs' claims were limited to theories of exposure based upon inhalation of enriched uranium released from the Apollo facility during its period of operation.[2] On April 12, 2013, an order was entered reassigning Judge Cercone as the district judge in all of the cases during the pendency and resolution of the Daubert motions and any motions for summary judgment that are filed.

In 1994, a prior case, captioned Hall v. Babcock & Wilcox Co., No. 94-951 ("the Hall case"), was filed arising out of similar claims. Over 500 plaintiffs sued B&W and Atlantic Richfield, alleging personal injuries and/or property damages arising out of emissions released from Apollo and Parks. In August 1998, Judge Ambrose presided over a jury trial of eight sample plaintiffs which resulted in a verdict for them. However, the defendants filed a motion for a new trial, which Judge Ambrose granted on June 29, 1999. In 2000, B&W filed a voluntary petition for protection under Chapter 11 of the Bankruptcy Code and all proceedings against it

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[1] For consistency, all citations are to the docket in the McMunn case, No. 10-143.

[2] A twelfth case, Ament v. Babcock & Wilcox Power Generation Group, No. 13-186, was filed on February 5, 2013. On April 25, 2013, a consent order was entered to apply the September 12, 2012 Memorandum and Order to the case. A thirteenth case, West v. Babcock & Wilcox Power Generation Group, No. 13-704, was filed on May 20, 2013. However, discovery has not been completed in these cases and expert reports have not been submitted. These cases are not included in this R&R.

were stayed. The plaintiffs reached a settlement with Atlantic Richfield, which Judge Ambrose approved on March 18, 2008. Finally, the plaintiffs reached a settlement with the reorganized B&W, which Judge Ambrose approved on April 17, 2009. This background is relevant because some of the same expert witnesses appeared in the Hall litigation, as will be discussed below.

On March 14 and March 18, 2013 motions to exclude various experts in these cases pursuant to Daubert were filed by Plaintiffs and Defendants. Specifically, Defendants moved to exclude Bernd Franke & Joseph Ring, Howard Hu, James Melius and Donal Kirwan. Plaintiffs moved to exclude John Till, Christopher Whipple & Stanley Hayes, Fred Mettler and John Boice. Oppositions were filed on April 15, 2013 and reply briefs were filed on April 22, 2013. A two-day hearing was held on April 30 and May 1, 2013, at which testimony was provided by: Dr. David Garabrandt, Dr. James Melius, Dr. Richard Toohey, Dr. Howard Hu, Dr. Stanley Marks and Dr. Fred Mettler. Post-hearing briefs were filed on May 31, 2013 and replies were filed on June 10, 2013.

Standard of Review

Federal Rule of Evidence 702 states that:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The Court of Appeals for the Third Circuit has explained that:

> "Rule 702 has three major requirements: (1) the proffered witness must be an expert, i.e., must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge [, i.e., reliability]; and (3) the expert's testimony must assist the trier of fact[, i.e., fit]." "Under the Federal Rules of Evidence, a trial judge acts as a gatekeeper to ensure that any and all expert testimony or evidence is not only relevant, but also reliable." Before the proposed testimony gets presented to the jury, the trial judge evaluates its admissibility based on these three requirements.

United States v. Schiff, 602 F.3d 152, 172 (3d Cir. 2010) (quoting Pineda v. Ford Motor Co., 520 F.3d 237, 243-44 (3d Cir. 2008)).

In these matters, the qualifications of the various experts are not disputed, but the parties contend that the testimony of the other side's experts is not based on methodology that is reliable and that the experts' testimony will not be helpful to the jury/trier of fact. In other words, the third requirement is at issue.

> It is typically understood in terms of whether there is a sufficient "fit" between the expert's testimony and the facts that the jury is being asked to consider. Daubert, 509 U.S. at 591, 113 S.Ct. 2786. In assessing whether an expert's proposed testimony "fits," we are asking " 'whether [the] expert testimony proffered ... is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.'" Id. (quoting United States v. Downing, 753 F.2d 1224, 1242 (3d Cir. 1985)). Put another way, this is a question of relevance, and "Rule 702, which governs the admissibility of expert testimony, has a liberal policy of admissibility" if it has the "potential for assisting the trier of fact." Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 806 (3d Cir. 1997) (citing Holbrook v. Lykes Bros. S.S. Co., 80 F.3d 777, 780 (3d Cir. 1996)); see also In re TMI Litig., 193 F.3d 613, 670 (3d Cir. 1999) ("expert evidence which does not relate to an issue in the case is not helpful"). The "standard is not that high," but "is higher than bare relevance." In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 745 (3d Cir. 1994).

Id. at 172-73.

In making its determinations, the court should apply Rule 702's requirements liberally, Pineda, 520 F.3d at 244, and should uphold the general framework of the Federal Rules of Evidence which favors the admissibility of evidence over nonadmissibility. Daubert, 509 U.S. at

588; see also Pineda, 520 F.3d at 243 ("The Rules of Evidence embody a strong preference for admitting any evidence that may assist the trier of fact.").

Where these requirements are not met, expert testimony should be excluded where it lacks the "proper relevance and 'fit' to the issues to be resolved by the trier of fact." Compagnie Des Bauxites De Guinee v. Three Rivers Ins. Co., 2007 WL 7626469, at *1 (W.D. Pa. June 8, 2007) (Cercone, J.) ("Without proper relevance and 'fit' to the issues to be resolved by the trier of fact, the proposed expert testimony on policy interpretation must be excluded.").

The Court of Appeals addressed a similar situation in In re TMI Litigation, 193 F.3d 613 (3d Cir. 1999), in which residents of the area around the Three Mile Island nuclear power plant brought suit alleging that the reactor accident on March 28, 1979 released radiation into the environment, causing them to develop neoplasms (unusual tissue growths). The plaintiffs brought suit under the Price-Anderson Act, the defendants raised Daubert challenges to the plaintiffs' experts, the district court excluded the overwhelming majority of the proposed experts' testimony as to dose exposure and the defendants then moved for and obtained summary judgment in their favor. The Court of Appeals affirmed.[3] A brief summary of some principles from that case follows.

As the Court of Appeals explained, the Price-Anderson Act, as amended in 1988, provided a federal cause of action for "public liability actions," and defined "public liability" as "any legal liability arising out of or resulting from a nuclear incident or precautionary

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[3] The court reversed the grant of summary judgment to the defendants as to the claims by the "non-trial plaintiffs" because it did not know what their trial theories would be. Id. at 723-27. However, ultimately, the district court concluded that the non-trial plaintiffs were proceeding with the same theories as the trial-plaintiffs and granted summary judgment against them again. The Court of Appeals affirmed. In re TMI Cases Consolidated II, 53 F. App'x 648 (3d Cir. 2002).

evacuation," except for certain claims covered by workers' compensation, incurred in wartime or that involve the licensed property where the nuclear incident occurs. Id. at 625 & n.9 (citing 42 U.S.C. § 2104(w)). The Act provides that "the substantive rules of decision in [any public liability action] shall be derived from the law of the State in which the nuclear incident involved occurs, unless such law is inconsistent with the provisions of [the Act]." 42 U.S.C. § 2014(hh). However, the Court of Appeals has observed that "Pennsylvania law does not change the federal standard for the admissibility of expert testimony." In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 761 n.31 (3d Cir. 1994).

When a radioactive nuclide, or radionuclide, decays, it may emit an alpha particle or a beta particle or gamma rays. Alpha particles "have a low level of energy and, therefore, are only capable of penetrating matter a small distance." 193 F.3d at 633 (footnote omitted). In fact, they "do not penetrate the layer of dead cells on the surface of the skin." Id. at 637 n.36. See also Mettler Decl. ¶ 14.[4]

The time required for one-half of a given sample of an element to decay is known as the "half-life." 193 F.3d at 632. Uranium 234, 235 and 238 have long half-lives. Id. at 632 n.24. Dr. Mettler explains that:

> The isotopes of uranium have long physical half-lives, as follows: uranium 238: $4.5 \times 10^9$ years; uranium 235: $7.1 \times 10^8$ years; and uranium 234: $2.5 \times 10^5$ years. All of these are very slow decay rates. For example, if one had 100 atoms of uranium 238 it would take about 4.5 billion years to decay to 50 atoms. Like natural uranium, enriched uranium decays very slowly. Enrichment removes daughter products (such as radon and radium isotopes) many of which have shorter half-lives. It also involves increasing the percentage composition of uranium 235 through the process of isotope separation.

Mettler Decl. ¶ 15.

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[4]ECF No. 204.

The court in TMI explained that radiation can cause cells to develop cancer, a "stochastic effect," namely an event that occurs at random rather than predictably. 193 F.3d at 642. Stochastic effects "are those whose probability of occurrence, as opposed to severity, is determined by dose." Id. at 640. The court noted that:

> Even at very low doses it is possible that ionizing radiation may deposit sufficient energy into a cell to modify it. Thus, there is a finite possibility for the occurrence of a stochastic event even at very small doses. Consequently, it is assumed that there is no threshold for the initiation of a stochastic event. Put another way, it is believed that stochastic effects can occur even at the lowest doses and, therefore, the possibility of a stochastic effect has to be taken into account at all doses. The probability that cancer will result from radiation increases proportionally with dose. However, it is currently believed that there is no threshold dose below which the probability of cancer induction is zero. It is presumed that any transformed cell can become cancerous and become a malignant tumor.

Id. at 642 (citations omitted).

Significantly, the court held that:

> Although there is scientific consensus that ionizing radiation can cause cancer, ionizing radiation is not currently known to leave a tell-tale marker in those cells which subsequently become malignant. Medical examinations and laboratory tests can determine the type and extent of a cancer, suggest an optimal treatment, and provide a likely prognosis, but they rarely (if ever) provide definite information as to its cause. Consequently, medical evaluation, by itself, can neither prove nor disprove that a specific malignancy was caused by a specific radiation exposure. Therefore, the primary basis to link specific cancers with specific radiation exposures is data that has been collected regarding the increased frequency of malignancies following exposure to ionizing radiation. In other words, causation can only be established (if at all) from epidemiological studies of populations exposed to ionizing radiation.
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> However, the task of establishing causation is greatly complicated by the reality that a given percentage of a defined population will contract cancer even absent any exposure to ionizing radiation. In industrialized countries where the life expectancy averages about 70 years, about 30% of the population will develop cancer and about 20% of the population will die of cancer. It is estimated that if 100,000 persons with an age and sex distribution typical of the United States are exposed to a whole body dose of 0.1 Sv and are followed over their lifetimes, between 770–810 people would develop fatal cancers in excess of the normal incidence.

Id. at 643-44 (emphasis added) (citations omitted). Thus, epidemiological studies are crucial to establishing causation.[5]

The court noted that radiation is a "constituent element of our environment, and mankind has been exposed to it since our first appearance on this planet." Id. at 644. The average annual dose of natural radiation in the United States is around 300 millirems, id. at 644 & n.50, to which medical irradiation (primarily from x-rays) added (at the time of the TMI case) an additional 40 to 100 millirems, id. at 647 & n.58. In this case, expert testimony was introduced that currently medical procedures provide an annual average of 300 millirems. (Hr'g Day 2 at 193-94.)[6]

"Uranium is found in various quantities in most rocks and soils, and it is the main source of radiation exposure to people out-of-doors." 193 F.3d at 645. The court noted that U-238, "the parent of the uranium series is the most abundant isotope, present in the amount of 99.28%, and it is in equilibrium with [U-]234, which is present in the amount of 0.0058%. Uranium–235, present in the amount of 0.71%, is the parent of the actinium series." Id. at 645 n.54. See also Mettler Decl. ¶ 13.

Upon consideration of all of these facts, the court held on a previous appeal that the plaintiffs had to show that:

> (1) the defendants released radiation into the environment in excess of the levels permitted by federal regulations in effect in 1979, i.e., 0.5 rems (500 mrems) or 5 mSv; (2) the plaintiffs were exposed to this radiation (although not necessarily at levels prohibited by those regulations); (3) the plaintiffs have injuries; and (4)

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[5] The court explained that epidemiology "is the study of the distribution and determinants of health-related states and events in populations and the applications of this study to control of health problems. Epidemiology is concerned with the incidence of disease in populations and does not address the question of the cause of an individual's disease." Id. at 660 n.81 (citation omitted).

[6] ECF No. 265.

> radiation was the cause of those injuries. We have also held that the "exposure element requires that plaintiffs demonstrate they have been exposed to a greater extent than anyone else, i.e., that their exposure levels exceeded the normal background level."

Id. at 659 (citing In re TMI, 67 F.3d 1103, 1119 (3d Cir. 1995)). It should be noted, however, that the plaintiffs in TMI alleged that their diseases were caused by gamma ray exposure from radioactive iodine, xenon and krypton, not alpha particle exposure from uranium. Id. Thus, Plaintiffs' statement in their post-hearing brief that "TMI itself involved uranium exposure" (ECF No. 269 at 3 n.4) is in error.

Individual discussion of the experts follows. The motions are addressed in the order in which they were filed, except that the challenge to Donal Kirwan (a damages expert) is addressed after the other expert witnesses.

Bernd Franke and Joseph Ring, Ph.D.[7]

Franke is a "radio-ecologist" who was retained by the Plaintiffs to provide an expert opinion that the amount of ionizing radiation in the form of enriched uranium that was released from the Apollo facility exceeded federal permissible regulations over the entire operational life of the facility. Plaintiffs claim that Franke recreated the numerical dose that an individual Plaintiff would have received as a result of a specific incident recorded in the Apollo facility's history. Franke previously co-authored a 1998 report, "Radiation Exposures in the Vicinity of the Uranium Facility in Apollo, Pennsylvania" ("1998 Report"), which he updated in his present affidavit.

According to Franke:

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[7] Defendants' challenge to Franke and Ring is based solely on the record; no testimony was presented by them at the hearing.

> The revised results clearly indicate that [a] short-term release of 3 kg of highly enriched uranium would have resulted in significant exposures and subsequent radiation doses to members of the public who were present in the vicinity of the plant during the accident. Up [to] and including 1979, the lung dose limits for residents was 1.5 rem; the accidental exposure could thus have resulted in doses that were up to 280 times larger than the permissible lung dose for 1963.

(Pls.' Opp'n Br. (ECF No. 235) Ex. 1 ¶ 7.)

Dr. Ring is a radiation safety officer with a doctorate in physics/radiological sciences who was retained by Plaintiffs to offer an expert opinion regarding alleged releases of radiation from Defendants' facilities at Parks and Apollo (i.e., a source term expert). Plaintiffs contend that Dr. Ring indicated that radioactive materials including plutonium and highly enriched uranium were used at both Parks and Apollo (Ring Rpt. at 5)[8]; that the operational, health and safety practices of the facilities did not comply with industry standards for much of the time they were operated (id. at 5, 9, 12); that the radiation protection programs were not adequate to monitor the radioactive material used and management knew this to be the case (id. at 5, 6, 21); that compliance records showed several large-scale releases of ionizing radiation into surrounding neighborhoods (id. at 5); that NUMEC was regularly issued violations of federal regulations and also regularly failed to comply with orders from the Atomic Energy Commission (AEC) and/or the Nuclear Regulatory Commission (NRC) on matters related to health and safety (id.); that NUMEC's environmental monitoring was also inadequate and improperly accounted for the extent of environmental releases (id. at 6); that NUMEC's failure to properly monitor and report levels of radiation led employees at the facilities to be placed in a special exposure cohort[9]

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[8] ECF No. 235 Ex. 2.

[9] "In epidemiology, a cohort is any designated group of persons followed or traced over a period of time to examine health or mortality experience." TMI, 193 F.3d at 706 n.151 (citation omitted).

by the United States Department of Health and Human Services and, as such, were "presumed to have sufficient radiation exposure to cause a reasonable likelihood it may have endangered their health" if they were employed 250 or more days at the plant (id.); that NUMEC's improper operations resulted in illegal dumping of radioactive materials in the soil and water around the plants and there were also excessive and unlawful emissions of radioactive materials from plant stacks (id.); that where monitored, data shows frequent unlawful emissions well above federal regulatory limits in unrestricted areas (id. at 7); that NUMEC affirmatively hid the nature and extent of violations of health and safety regulations (id.); that at one point, NUMEC had the highest level of nuclear "Materials Unaccounted For" ("MUF") of any facility in the United States (id.); and, that "Based on the inadequate monitoring system, large number of unmonitored release points, and significant quantities of radioactive materials deposited in the ventilation system, and in view of NUMEC's failure to provide a plausible explanation for the MUF, it is reasonable to infer that most of this MUF was released into the communities surrounding these facilities." (Id.)

Defendants move to exclude the reports of Franke and Ring on the grounds that they did not perform a dose-specific calculation for each Plaintiff, did not read depositions or questionnaires, and relied upon a hypothetical "scenario calculation" with no basis in fact and therefore produced a result without a scientific basis. Defendants contend that the opinions of Franke and Ring do not "fit" these cases. Franke and Ring both confirmed that dose is the "starting point of any causation analysis." (Ring Dep. I at 183:4-15; Franke Dep. I at 40:9-13.)[10]

Defendants note that Franke was hired in the Hall case to develop opinions about the

[10] Phillips Decl. (ECF No. 203) Exs. A, C.

amount of uranium that was released from the Apollo facility during its years of operation and to calculate a radiation dose to each plaintiff, unlike here. He prepared a "dose assessment" for each plaintiff, applied each plaintiff's exposure profile to a well-accepted methodology and calculated radiation doses to the specific organ that was relevant to the cancer alleged by each plaintiff and summarized his opinions in a 92-page Rule 26 report. (Franke Dep. I at 40:19-21.) Here, by contrast, Franke submitted only a 2-page Rule 26 report, in which he simply updated a "scenario dose calculation" that he had prepared for his 1998 report based on the assumption that a hypothetical person was standing at the boundary of the Apollo facility on February 9, 1963 and inhaled uranium supposedly released during a vault fire. (ECF No. 203 Ex. F.) Franke updated his 1998 "scenario calculation" by applying the latest internal dosimetry[11] model developed by the International Committee on Radiological Protection ("ICRP") (known as ICRP 72) for purposes of completing a hypothetical dose calculation. His 2012 Report reflects all the opinions he developed for this case, and there were no limitations placed on the amount of time he could spend completing his work. (Franke Dep. I at 146:3-5; Franke Dep. II at 194:17-22.[12])

In his 2012 Report, Franke also incorporated by reference most of the 1998 Report he prepared for the Hall litigation. (ECF No. 203 Ex. G) (modified version of 1998 Report attached as exhibit to two-page 2012 Report). Before doing so, however, he removed the appendix containing the plaintiff location data used to calculate exposure assessments for the Hall plaintiffs. Id. Franke indicated in his 2012 Report that he was "prepared to provide a detailed assessment of the radiation exposures for specific individuals who lived near the Apollo and

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[11] "Dosimetry is the science of determining radiation fields and dose to individuals, or materials, by using any and all known types of detectors and calculational techniques." TMI, 193 F.3d at 699 n.140 (citation omitted).

[12] ECF No. 203 Ex. D.

Parks facilities once [he] receive[s] more information about the circumstances of the individuals at issue (age at exposure, location, residence time, living habits etc.)." (2012 Rpt. ¶ 9.)[13] However, Defendants note that he did not conduct an exposure or dose assessment for any Plaintiff as he did in Hall. Franke was not asked to perform any Plaintiff-specific dose calculation. See Franke Dep. I at 50:2-5 ("And just to close this out, you did not do any dose calculation or exposure estimate for any specific plaintiffs in this case? A: That's correct."). During his most recent deposition, Franke made clear that he does "not expect to be asked about radiation exposures of individual plaintiffs." (Franke Dep. II at 21:14-22.)

Defendants note that, each Plaintiff, before his or her respective deposition, completed detailed questionnaire responses that provided address information, work information, school location, and dates of diagnoses for the specific type of cancer for which the Plaintiff is seeking recovery. See, e.g., ECF No. 203 Ex. H (Third Supplemental Plaintiff Questionnaire of Patricia Ann Altmire). But Franke was unaware that the questionnaire responses existed and made no attempt to review them. (Franke Dep. I at 37:13-16) ("I am not aware of that.")

Franke also failed to request or review deposition testimony from any Plaintiff. Building on their questionnaire responses, each Plaintiff provided additional information during their respective depositions about where they lived, where they worked, where they went to school, and how much time they spent at each location. Each Plaintiff identified these key locations on large maps of the Apollo area that were attached as an exhibit. See, e.g., ECF No. 203 Ex. I (copy of Exhibit PA 17 from the November 1, 2011 Deposition of Patricia Altmire). As with the questionnaire responses, Franke was unaware that the depositions occurred, did not read a single

[13] ECF No. 203 Ex. F.

transcript, and was not asked by Plaintiffs' counsel to review them. (Franke Dep. I at 37:5-12) ("I was not told that [Plaintiffs] were deposed and I wasn't asked to read the depositions if they exist."). Franke neither obtained nor reviewed information about where a particular Plaintiff was located at any given time while the Apollo facility was operating. (Franke Dep. I at 148:23-149:2.)

Defendants argue that, to calculate an organ-specific dose to the part of the body where each cancer originated, Franke would have had to first determine each Plaintiff's diagnosis in order to identify the relevant organ to which the dose should be calculated using recognized ICRP models. (Mettler Decl. ¶¶ 6-8; Toohey Decl. ¶ 11[14].) The effect of a given dose depends on the tissue or organ exposed to the radiation. In re TMI, 193 F.3d at 638. Franke did not determine the relevant cancers or identify the organs of interest relevant to each Plaintiff. (Franke Dep. I at 42:16-43:7) (confirming no knowledge of relevant Plaintiff organs).

Dr. Toohey faults both Franke and Ring for failing to calculate dose, which can be done easily using a scientifically-accepted method for dose reconstruction which he outlines. (Toohey Decl. ¶¶ 12-14.) "Dose reconstruction is defined as the process of estimating doses to the public from past releases to the environment of radionuclides…. These doses form the basis for estimating health risks and for determining whether epidemiological studies are warranted." TMI, 193 F.3d at 671 n.98 (citation omitted).

Franke's two-page 2012 Report consists almost entirely of an updated "scenario [lung dose] calculation" to a hypothetical person located along the Apollo site boundary during fifteen minutes on February 9, 1963. (2012 Report ¶ 6; Franke Dep. I at 41:21-25.) He admitted

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[14] ECF No. 208.

that his scenario calculation from the 1963 event was to a "hypothetical person, not an actual plaintiff in this case." Id. at 83:9-14. He did not associate his hypothetical, "scenario calculation" to any Plaintiff. Id. at 83:5-19 (he did not determine whether any Plaintiff in this case was among the "members of the public" potentially exposed to the 1963 release).

Defendants argue that Dr. Ring's opinions are unrelated to the Plaintiffs. He did not address the question of Plaintiffs' potential exposures, nor did he "specifically calculate a dose" for any Plaintiff. (Ring Dep. II at 37:20-25) ("Definitely did not do exposure opinions."); Ring Dep. I at 65:18-20; 88:23-89:5 (confirming no opinion about general or organ-specific doses for Plaintiffs); id. at 187:18 ("I didn't look at dose."). His Rule 26 expert opinions are narrow in scope and focused solely on "radiation control practices" at the Apollo facility. See Ring Dep. I at 51:18-20 ("I was asked to take a look at the radiation control practices, and I looked at the radiation control practices."); id. at 52:3-4 ("I looked at the radiation control practices."); id. at 59:21-22 ("I would say the focus [of my work] is on the radiation protection practices."); id. at 65:19-20 ("I looked at the radiation protection practices only."); id. at 66:2-3 ("[r]adiation protection practices only"); id. at 87:12-13 ("I looked at the radiation control practices."); id. at 197:18-19 ("I was asked to provide a review on radiation protection practices."); and Ring Dep. II at 38:13-17 (Q: "And again, as you told me last time, your focus in the case was to [ ] address radiation protection practices that were employed at the Apollo facility?" A: "Yes, that is correct.").

For this reason, he did not review Plaintiffs' questionnaire responses, depositions, or medical records to determine the relevant cancers or organs of interest (Ring Dep. I at 79:4-80:12), and he admits that no aspect of his work relates to a single Plaintiff. Put differently, Dr. Ring confirmed that his opinions have nothing to do with what occurred beyond the boundary of

the Apollo facility. (Ring Dep. II at 141:10-15; 151:7-13; 154:4-155:7.) Dr. Ring indicated that Plaintiffs placed no constraints on his work. (Ring Dep. I at 44:4-5; Ring Dep. II 134:14-21.)

Plaintiffs respond that their testimony "fits" because it would aid the jury in determining if Plaintiffs were injured by ionizing radiation in the form of enriched uranium which exceeded federal regulations over the operational life of the Apollo facility. They contend that Franke recreated the dose an individual Plaintiff would have received based upon a specific incident (the vault fire in 1963) and that Dr. Ring opined on radiation protection practices in place at Apollo (and Parks).

Plaintiffs argue that Franke's findings demonstrate that Defendants regularly and repeated violated the standard of care identified in 10 CFR § 20.105 & 10 CFR § 20.106; this evidence is clearly relevant to, and complies with, the Court's ruling an order of September 12, 2012; Franke's opinion is directly applicable to proving that Defendants breached their duties to Plaintiffs and the public. In addition, Franke identifies the specific radionuclide—highly enriched uranium—and the plant from which it originated—Apollo; Franke's expert opinion is directly relevant to these elements of Plaintiffs' case; and finally, Franke's soil analysis along with the work of Dr. Ketterer demonstrate the geographic extent of the contamination plume from Defendants' facilities to which Plaintiffs, present at the time, would have been exposed to Defendants' ionizing radiation. Therefore, Plaintiffs contend his opinion is crucial to their case. They also argue that Dr. Ring found that the relatively few monitored emissions regularly exceeded federal limits, thereby supporting a claim that Defendants breached the standard of care under Price-Anderson.

In their reply brief, Defendants note that Plaintiffs do not dispute that they must offer evidence of dose in order to prove causation and that they must demonstrate that their exposure

levels exceeded background radiation. To the extent that Plaintiffs argue that Franke "recreated the numerical dose that an individual plaintiff would have received as a result of a specific incident recorded in the Apollo facility's history," Defendants respond that this statement is false and refuted by Franke himself. At his deposition, he stated that he "did not do any dose calculation or exposure estimate for any specific plaintiffs." (Franke Dep. I at 50:2-5; Franke Dep. II at 21:14-22.) Moreover, Franke admitted that the 1963 scenario Plaintiffs reference related to a "hypothetical person, not an actual plaintiff in this case." (Franke Dep. I at 83:5-14.) He never offered the opinion that a particular Plaintiff in this case was near the Apollo facility during this incident, nor did any other expert. Similarly, Dr. Ring limited his expert opinion to the "radiation control practices" at the Apollo facility and did not analyze areas outside the boundary of the facility where a particular Plaintiff may have been located. (Ring Dep. II at 151:7-13.) Franke was not retained to provide a source term opinion regarding the Apollo facility and Dr. Ring testified that he has no opinion about whether uranium was released from Apollo in excess of the relevant annual regulatory limits, which is necessary to maintain a claim for breach of duty. (Ring Dep. I at 57:16-58:2.)[15]

At the hearing, Dr. Toohey repeated his criticism of Dr. Ring for failing to calculate the dose and noted that Franke had said he was prepared to calculate dose, but was not asked to do so. He rejected the idea that it is not necessary to know the amount of exposure in order to link uranium to cancer, stating that "You need to know the dose that was absorbed in the specific organ in which the cancer arose." (Hr'g Day 2 at 10-12.) He explained that "exposure" to radiation (being in the presence of it) is not the same as dose, a calculation of the amount of

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[15] Phillips Reply Decl. (ECF No. 251) Ex. 2.

radiation absorbed per gram of tissue by the affected organ. (Hr'g Day 2 at 7-8.) He explained that ICRP and the NRC and other agencies have published tables of dose coefficients which relate radiation dose to intake. The Health Physics Society (HPS), the National Council on Radiation Protection and Measurements (NCRP) and the National Academy of Sciences have issued position statements indicating that dose must be considered in determining whether to provide compensation for a disease that could have been caused by radiation. (Hr'g Day 2 at 8-9.) Dr. Toohey noted that Franke used a vault fire that occurred in 1963 to guess at a uranium release, but did not link it to a dose received by any individual. (Hr'g Day 2 at 12-13.)

As noted above, everyone receives a dose of radiation from background sources, both natural and man-made. TMI, 193 F.3d at 644. Therefore, an individual's dose above this background amount must be calculated to assess causation. Id. at 659. See Mettler Decl. ¶¶ 5-8; Toohey Decl. ¶¶ 7-11. For example, the HPS published a position statement in 2000 entitled "Compensation for Diseases That Might Be Caused by Radiation Must Consider the Dose," in which it stated that: "Based on the extensive knowledge of radiation health effects, the Health Physics Society believes that a person's radiation dose must be considered in determining whether to provide compensation for a disease that could have been caused by radiation." (Toohey Decl. Ex. 2 at 1.)

Consistent with the HPS' Position Statement, the National Research Council's Biological Effects of Ionizing Radiation (BEIR) VII Report (2006), entitled "Health Risks From Exposure to Low Levels of Ionizing Radiation," confirms the critical importance of exposure and dose information when assessing whether science supports the claim that radiation caused a particular individual's cancer:

When the complete body of research on [radiation effects] is considered, a

> consensus view emerges. This view says that the health risks of ionizing radiation, although small at low doses, are a function of dose…. Other work in epidemiology also supports the view that the harmfulness of ionizing radiation is a function of dose.

(Toohey Decl. Ex. 4 at 10.)

Similarly, the NCRP, in its Report 163 (2009) entitled "Radiation Dose Reconstruction: Principles and Practices," states that "dose" is the pertinent inquiry when asking the question of whether an individual's cancer was caused by exposure to radiation:

> The health outcomes attributable to exposure to ionizing radiation can be either deterministic (*e.g.*, cataracts, blood cell dyscrasias) or stochastic (*i.e.*, cancer) in nature. In either situation, however, it is necessary to establish the magnitude of the dose received by the individual under evaluation, so that an accurate decision regarding compensability can be made.

(Toohey Decl. Ex. 3 § 7.5.1.)

In their post-hearing brief, Plaintiffs refer to a specific individual, Thomas Toland, who lived near the Apollo plant at the time of the 1963 vault fire and who, they contend , "would have received up to 420 rem of exposure from this event alone." (ECF No. 268 at 1 n.1.) Defendants respond that: Franke did not actually determine that Mr. Toland received this dose; Franke's hypothetical dose is a lung dose while Mr. Toland developed kidney cancer; their experts calculate that Mr. Toland's kidneys received 23 millirems or less over a 24-year period and thus the probability that this dose caused his kidney cancer would be 0.012%; and they calculated that if he was present for the vault fire his lungs would have received a dose of 0.04 millirem, which is less than the average person's daily background natural radiation dose. (ECF No. 237 Ex. A at 8-3, ECF No. 248 Ex. A at 47, ECF No. 237 Ex. A at Table E-6.)

In addition, Plaintiffs submit numerous additional documents not previously referenced or discussed in their prior briefing or at the hearing to show that NUMEC released radioactive

materials into the environment around the Apollo facility, that such releases were ineffectively monitored and that internal communications acknowledged the inadequacy of the monitoring. (ECF No. 268 Exs. A-R, BB-EE.) Defendants respond that Plaintiffs, in focusing on these isolated incidents, have ignored hundreds of thousands of pages of stack, vent and environmental data establishing that offsite contamination did not violate regulatory limits. (Till Rpt. Ch. 12; Environ Rpt. at 2 ¶¶ 2-4, 3 ¶ 6, 14-15 ¶¶ 50-52.)

"The severity of the effect is dependent upon the dose." TMI, 193 F.3d at 641. This requires that plaintiffs "demonstrate that they have been exposed to a greater extent than anyone else, i.e., that their exposure levels exceeded the background level." Id. at 659 (citation omitted). In the TMI case, the plaintiffs relied in part on the expert testimony of Charles Armentrout, who prepared a report about two "anomalous bursts" of radiation activity near Portland, Maine, that the plaintiffs were attempting to connect to the "TMI plume" from Pennsylvania passing over the northeastern part of the United States. The court stated that:

> Armentrout merely assumed that his observations of two bursts of radiation activity were the result of the TMI plume passing over his area of southern Maine. That assumption is supported by nothing other than conjecture, and we do not believe that the District Court erred in ruling the evidence inadmissible under Rule 702.
>
> Moreover, assuming arguendo that Armentrout's opinion that the TMI plume passed over the northeast United States has scientific reliability, his opinion still would not be helpful to the trier of fact. The Trial Plaintiffs proffered Armentrout's testimony in an effort to demonstrate that they were exposed to levels of radiation sufficient to cause their injuries. They based their trial strategy on the theory that as a result of the accident, they were exposed to an equivalent dose of at least 10 rems or 100 mSv each. However, Armentrout admitted that he could not tell with any degree of scientific certainty how large the radioactive releases from the accident were. The connection between his testimony and a crucial fact in issue, i.e., whether the Trial Plaintiffs were exposed to equivalent doses of 10 rems or 100 mSv each was tenuous at best because he could not testify as to the magnitude of the releases of radionuclides.

Id. at 674 (footnote omitted).

Defendants have demonstrated that the proposed testimony of Franke and Dr. Ring does not survive a challenge under Daubert. They did not calculate the dose received by any Plaintiff in these cases. Franke does not even assume that Plaintiffs were present for and exposed to the vault fire in 1963. Moreover, even if he did so, his assumption would be supported by nothing more than conjecture, like Armentrout's assumption in the TMI case. Dr. Ring discusses radiation control practices at Apollo, but does not connect his findings to any Plaintiff. Their testimony does not "fit" the breach of duty element of Plaintiffs' claims because without a calculation of dose, it would not aid the trier of fact in resolving the issue of causation. Therefore, the motion to exclude their testimony under Daubert should be granted.

Howard Hu, M.D., M.P.H., Sc.D.

Dr. Hu is a physician and an environmental and occupational epidemiologist who holds degrees as a Doctor of Science and Master of Public Health. He was hired by Plaintiffs as their general causation expert. He has never conducted research regarding health effects from uranium exposure and he has never designed or conducted an epidemiological study of a population exposed to ionizing radiation. (Hu Dep. at 149:3-153:1.)[16] He is not a radiation or cancer epidemiologist and he has not published any original research regarding whether any form of radiation causes cancer, nor has he published any peer-reviewed articles regarding his litigation opinion that uranium causes numerous types of cancer. (Hu Dep. at 13:7-14:9, 371:12-16.)

Dr. Hu opines that: the Apollo plant emitted a mixture of radionuclides, including

[16] Meier Decl. (ECF No. 212) Ex. B.

substantial amounts of highly enriched uranium; radionuclides are known to increase the risk of developing cancer based on their property of emitting ionizing radiation in the form of alpha and beta particles and their ability to be absorbed by the human body through inhalation or ingestion and widely distributed to tissues throughout the body; the ability of highly enriched uranium to cause cancer is supported by its well-known emission of ionizing radiation as well as specific experimental and epidemiologic studies; this radiation could be expected to increase the risk of any of the 22 cancers alleged by the Plaintiffs in these cases; regarding an individual who lived, worked or otherwise spent an significant amount of time within the likely exposure area and who subsequently developed a cancer associated with ionizing radiation, it "would be reasonable to conclude that ionizing radiation exposure from the emission of radionuclides from the Apollo nuclear plant may have constituted a substantial contributing factor towards the causation of the cancer"; and that the studies conducted by Dr. Boice and the Pennsylvania Department of Health (PDH) do not contradict his opinion because they are subject to a large number of limitations related to the general methodologic issues of ecologic epidemiology studies as well as specific additional limitations and incorrect assumptions related to the research designs of these same studies. (Hu Rpt. at 14.)[17]

Defendants challenge his testimony on the ground that, although he admits that the Bradford Hill[18] criteria set the "gold standard" for determining causation, he did not use them in this case and he acknowledges that they could not be met. (Hu Dep. at 336:20-338:4.) His

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[17] ECF No. 212 Ex. C.

[18] As Dr. Hu explained in his affidavit proffered in Brown v. NL Industries in 2009, the Bradford Hill criteria, which set the gold standard for determining causation in evidence-based medicine, are named for Sir Austin Bradford Hill, a British statistician who was knighted for his work in public health and epidemiology. (ECF No. 212 Ex. A ¶ 14.)

subjective beliefs as to causation are not admissible. He failed to ground 20 of the 21 cancer types on epidemiological studies, conducted a selective review and failed to address studies that were contrary to his analysis and relied on a report by the International Agency for Research on Cancer (IARC), a division of the World Health Organization (WHO), in a manner which was inconsistent with his approach elsewhere and is untestable. Defendants note that he has previously testified as an expert regarding causation of injuries in cases involving exposure to lead and in that case he used the Bradford Hill criteria. (Hu Dep. at 119:19-120:22.) The Court of Appeals has explained that the "Bradford Hill criteria are 'broadly accepted criteria for evaluating causation that have been developed by scientists such as Sir Bradford Hill." Gannon v. United States, 292 F. App'x 1709, 173 n.1 (3d Cir. 2008). As Dr. Mettler explained:

> In 1965, Sir Austin Bradford Hill published a method for addressing general causation that involves nine criteria of associations that scientists should consider before deciding that the most likely interpretation of the association is causation: (1) Strength of Association; (2) Consistency; (3) Specificity; (4) Temporality; (5) Dose-response or biologic gradient; (6) Biologic plausibility; (7) Coherence; (8) Experimental evidence; and (9) Analogy. The "Bradford Hill criteria" are commonly used by epidemiologists today to render general causation determinations.

(Mettler Decl. ¶ 16.) See also Garabrandt Decl. ¶ 9.[19]

These criteria allow epidemiologists to test whether an alleged association[20] is causal. Amorgianos v. Nat'l R.R. Passenger Corp., 137 F. Supp. 2d 147, 168 (E.D.N.Y. 2001); see also In re Avandia Mktg., Sales Practices and Prods. Liab. Litig., 2011 WL 13576, *3 (E.D. Pa. Jan. 4, 2011) ("Bradford–Hill criteria are used to assess whether an established association between

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[19] ECF No. 213.

[20] The Court of Appeals noted in TMI that "association" is a term of art in epidemiology meaning that events occur more frequently than one would expect by chance, but does not necessarily imply a causal relationship. 193 F.3d at 710 n.159.

two variables actually reflects a causal relationship."). Therefore, "before determining whether an agent causes a disease, an epidemiologist will first address whether there is an association between the agent and the disease." Beckwith v. Matrixx Initiatives, Inc., 467 F. Supp. 2d 1316, 1327 (M.D. Ala. 2006) (citation omitted). If an association has been found between a substance and a type of disease, the epidemiologist must then apply the Bradford Hill criteria to determine whether the relationship is causal, rather than due to chance or confounding factors. See Soldo v. Sandoz Pharm. Corp., 244 F. Supp. 2d 434, 461 (W.D. Pa. 2003) ("However, application of the Bradford Hill criteria depends first upon an association by epidemiology between a disease and an exposure to an agent. The association must rule out chance.").

The analysis proceeds in two steps. Step one looks to whether there is a statistically significant association between a substance and a specific disease. See Soldo, 244 F. Supp. 2d at 533 ("Courts have emphasized that epidemiologic proof must be statistically significant."). If no association between the exposure and the disease is supported by the scientific literature, there is no basis to find a causal relationship exists and the analysis should end there. Dunn v. Sandoz Pharm. Corp., 275 F. Supp. 2d 672, 679 (M.D.N.C. 2003) (excluding general causation opinion of expert who purported to apply Bradford Hill criteria, but could not cite any epidemiological studies showing association between substance and disease at issue). If an association between the exposure and the disease exists, the second step applies the Bradford Hill criteria to assess whether the relationship is causal. Soldo, 244 F. Supp. 2d at 461 ("[A]pplication of the Bradford Hill criteria depends first upon an association by epidemiology between a disease and an exposure to an agent.").

Dr. Mettler states that:

> For purposes of determining health effects from radiation exposure, the

total, organ-specific dose is based on the activity of the uranium inhaled by the individual. Reflecting this fact and the common radiological properties of isotopes of uranium, national and international organizations responsible for evaluating health effects from radiation exposure have included information from studies involving exposures to natural uranium in evaluating potential hazards from exposure to all forms of uranium, including enriched uranium.

I have reviewed the epidemiologic literature concerning cancer risks among workers who are exposed to uranium in uranium processing facilities, uranium milling plants, uranium weapons plants, and in communities near such facilities. There are well over a dozen such studies, and they have consistently found no association between uranium and any cancer. Each of these studies involved uranium doses to workers that likely were higher than those estimated to have been received by Plaintiffs in this case.

I have reviewed the report and opinions of plaintiffs' expert Dr. Howard Hu in these cases. Dr. Hu offers the opinion that highly-enriched uranium is capable of causing cancer by virtue of its emission of alpha particles. To reach this opinion, Dr. Hu attempts to link studies of "ionizing radiation" and "alpha emitting radiation" to an increased incidence of cancer, despite the absence of evidence that any radionuclide other than uranium was allegedly released to the environment from the Apollo facility. Because there is extensive epidemiologic literature for uranium, it is not necessary or appropriate, as Dr. Hu does, to look to alpha emitters generally for information regarding causal effects of uranium.

(Mettler Decl. ¶¶ 17-19.)

Dr. Toohey states that:

Dr. Hu has failed to establish that exposure to uranium is capable of causing cancer. He ignores the epidemiologic literature indicating that uranium exposure has not been shown to cause cancer in humans. Dr. Hu justifies this failing by insisting that studies of populations exposed to natural uranium are inapplicable to populations exposed to highly enriched uranium. The animal studies he cites do not support his claim.

Dr. Hu falsely claims that exposure to enriched uranium carries a much higher risk of cancer than exposure to the same amount of natural uranium. In support of this proposition, Dr. Hu cites animal studies in which rats were administered enriched uranium and then irradiated, which produced much higher radiation doses than those resulting from any uranium released from the Apollo facility. In one of these studies, the rats were exposed to natural uranium (U-238) and enriched uranium (U-235) then placed in a reactor where neutrons caused fission of the U-235 atoms. The authors concluded that the study suggested that fission fragments (not at issue here), rather than alpha particle emissions, may

> have contributed to the lung cancers observed in the rats. In the other study relied upon by Dr. Hu, there was no comparison between natural uranium and enriched uranium. Thus, it is clear that these studies did not purport to measure the health effects of natural uranium and enriched uranium based on their alpha-particle emissions. These studies do not support Dr. Hu's claim that exposure to enriched uranium has a more significant radiobiological effect than natural uranium.
>
> Similarly, Dr. Hu tries to draw a distinction between enriched uranium and natural uranium by claiming that a small amount of enriched uranium produces the same dose as a larger amount of natural uranium – on a mass basis. For purposes of assessing potential health effects, however, this distinction is a false one. It is well-accepted by consensus scientific bodies that when assessing the potential radiobiological effects from exposure to a radionuclide like uranium, one must use activity units, rather than mass units. For purposes of comparing natural uranium to enriched uranium, the dose conversion factors for the various isotopes are essentially identical. Moreover, at the very low doses at issue in this litigation, any difference between dose per unit of activity from natural uranium versus highly enriched uranium is negligible from a radiation protection standpoint. The difference is even less significant when one considers the fact that much of the uranium processed at the Apollo facility was low-enriched uranium.

(Toohey Decl. ¶¶ 21-23.) He also criticizes Dr. Hu (and Dr. Melius) for finding general causation as to the 22 cancers compensable under a federal nuclear workers' compensation program, the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), noting that this conclusion is based on a misinterpretation of the development of the list of 22 compensable cancers and the policy decision behind identifying presumptive cancers:

> The listed cancers were selected based on significantly increased incidence in populations exposed to ionizing radiation, primarily the Japanese atomic bomb survivors and patients exposed to high doses of medical radiation (usually in the form of neutron, gamma and/or x-radiation, as opposed to alpha radiation). No governmental or scientific body, to my knowledge, has endorsed the use of the EEOICPA list outside of the worker compensation context.

(Toohey Decl. ¶ 19.) See also Toohey Rpt. at 15-16 (Toohey Decl. Ex. 1.) As Defendants observe, federal regulations do not anticipate that EEOICPA findings will be used in litigation. See 67 Fed. Reg. 22,296, 22,300 (May 2, 2002) (the Department of Health and Human Services "does not believe these findings should be used for any purpose other than adjudication of claims

under EEOICPA.")

Dr. Garabrandt states that: Dr. Hu did not perform a systematic review of the relevant scientific literature; Dr. Hu improperly cited only a small fraction of the epidemiologic studies that have evaluated whether uranium exposure is causally associated with the cancers at issue; and that a proper analysis of all the literature shows no reliable association between uranium exposure and cancer; Dr. Hu improperly relied on reports and studies which deal with exposure to ionizing radiation generally, rather than exposure to uranium specifically; Dr. Hu failed to consider all the issues that are widely accepted by the scientific community as relevant to whether there is a causal relationship between the substance and human disease, specifically the Bradford Hill criteria; and Dr. Hu failed to adequately analyze the uranium exposure levels that are associated with increased risk of the cancers at issue in this case. (Garabrandt Decl. ¶ 11.)

Plaintiffs respond that, as Defendants admitted in their litigation with their insurer in the Hall settlement, Dr. Hu recognized that ionizing radiating, including emission of alpha particles, causes cancer in humans and uranium is a known emitter of alpha particles. They dispute that Dr. Hu is required to base his opinion on epidemiology specific to uranium, noting that the National Institute for Occupational Safety and Health (NIOSH) uses Hiroshima and Nagasaki risk models and that enriched uranium is different from the natural uranium and low-enriched uranium used in various studies. They contend that the Bradford Hill criteria are not used on individuals but on the group as a whole, that IARC uses it in this manner and that the case cited by Defendants, Cano v. Everest Minerals Corp., 362 F. Supp. 2d 814 (W.D. Tex. 2005), was decided under Texas law and has been questioned. Finally, they contend that EEOICPA uses this data and there is no reason not to use it to resolve issues of general causation, although it cannot be used for specific causation.

In their reply brief, Defendants note that Dr. Hu failed to follow his normal methodology for finding general causation (the Bradford Hill criteria) and that Plaintiffs rely on the proposition that "radiation is radiation," but national and international organizations responsible for radiation safety have evaluated uranium separately for carcinogenesis and found the evidence lacking and courts have excluded expert opinions that were not derived using an expert's normal methodology. After reviewing dozens of epidemiological studies that followed hundreds of thousands of uranium workers for decades to determine whether they were at an increased risk of cancer due to their exposure to uranium (including enriched and highly enriched uranium), the United Kingdom's Royal Society on the Health Hazards of Uranium (the "Royal Society") concluded that:

> [T]here is no evidence of a significant increase in deaths from any cause, or from all cancers, or individual types of cancers, or genitourinary disease (including kidney dysfunction), in the large cohorts of uranium workers whose health has been monitored, in many cases for several decades…. Studies of the health of workers in the uranium industry therefore show no sign of excess deaths due to cancer or kidney disease related to inhaling or ingesting uranium.

(Garabrandt Decl. ¶ 10(a), Ex. B at 18.) Similarly, IARC has found that there is "inadequate" evidence regarding carcinogenicity in humans for "uranium and its decay products, inhalation of ore dust containing uranium-234, uranium-235 and uranium-238." (ECF No. 212 Ex. E (IARC Vol. 78, Ionizing Radiation, Part 2: Some Internally Deposited Radionuclides, at 481.)

Although Dr. Hu criticizes the uranium worker studies as inadequate to determine the carcinogenicity of uranium, that criticism in turn does not advance Plaintiffs' case. The lack of scientific evidence that a substance causes a disease does not permit an expert to opine that further "adequate" studies would show a causal relationship: "While such speculation is appropriate in the laboratory where a hypothesis can be tested by experiment, it has no place in

the courtroom where no such testing is possible." Perry v. Novartis Pharm. Corp., 564 F. Supp. 2d 452, 469 (E.D. Pa. 2008). Moreover, the Perry court noted that an expert cannot ignore the published epidemiological studies that are contrary to the expert's opinion, noting that "while an expert's conclusions reached on the basis of other studies could be sufficiently reliable where no epidemiological studies have been conducted, no reliable scientific approach can simply ignore the epidemiology that exists." Id. at 465. See also Cano, 362 F. Supp. 2d at 851 ("This failure to consider both positive and negative associations in the literature is not reliable methodology….") Defendants point out that Dr. Hu has ignored not just one uranium study, but more than a dozen epidemiologic studies of persons exposed to uranium.

The United Nations Scientific Committee on the Effects of Atomic Radiation ("UNSCEAR") evaluated uranium separately from other radionuclides and concluded that:

> There appear to be several possible reasons why uranium is not conclusively found to cause cancer in humans and why it is not considered a human carcinogen: uranium is not very radioactive (having such a long half-life of billions of years, U-238 decays very slowly), and its chemical properties are often such that any inhaled or ingested uranium is excreted rather quickly from the body. Some compounds of uranium are relatively insoluble and can be retained in the body. Nonetheless, there is little or no epidemiological evidence for an association between uranium and any cancer.

(Garabrandt Decl. ¶ 10(b), Ex. C, UNSCEAR 2006 Report, at 53 ¶ 130.)

Dr. Hu admits that he is "not aware of any peer reviewed medical or scientific literature that states that highly enriched uranium causes each of the types of cancers" at issue in his report. (Hu Dep. at 371:17-21.) Nor can he name any consensus scientific organizations that agree with him that uranium is a human carcinogen. (Hu Dep. at 276:5-19.) Moreover, Dr. Hu's hypothesis that uranium causes cancer throughout the body cannot be tested using the Bradford Hill criteria and Dr. Hu indicated that he did not test his hypothesis that uranium caused each Plaintiff's type

of cancer. (Hu Dep. at 377:20-24.) Defendants maintain that Dr. Hu acknowledged that the biologic effect of different radionuclides depends on their radioactivity and chemical properties. (Hu Dep. at 173:23-75:1.) In an article he co-authored regarding ionizing radiation, Dr. Hu distinguished between gamma radiation, which "can affect DNA in blood-forming cells or in many organs in ways that cause cancers of these organs decades later," and other forms of radiation, and also noted that "tissues vary in their sensitivity to radiation damage." (Sumner, D., Hu, H. & Woodward, A., Health Risks of Ionizing Radiation, Science for Democratic Action, 8:4, at 6-7 (2000).[21]

In Cano v. Everest Minerals Corp., 362 F. Supp. 2d 814 (W.D. Tex. 2005), the court held that, because IARC had found "that the degree of evidence of carcinogenicity of uranium and its decay products, inhalation of ore dust containing uranium-234, uranium-235 and uranium-238 is 'limited' in animals and 'inadequate' in humans," it would be "unreasonable to rely on more general statements in the paper that 'internalized radionuclides that emit alpha particles and beta particles are carcinogenic to humans' to support a conclusion that natural uranium exposure caused cancer in these Plaintiffs." Id. at 852. Defendants respond to Plaintiffs' criticism by noting that the Cano court did not rely on Texas law regarding "doubling dose" or any other rule from Texas law as the basis for excluding the plaintiffs' expert opinions on uranium general causation as unreliable under Daubert. They also note that another court has already excluded Dr. Hu's testimony on general causation based on similar considerations. See Zabilansky v. American Bldg. Restoration Prods., Inc., 2006 WL 2520288, at*2 (Mass. App. Ct. 2006); ECF No. 255 Exs. 3, 4, 5.

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[21] Meier Reply Decl. (ECF No. 255) Ex. 2.

Defendants also note that the Court of Appeals in TMI did not hold that all "ionizing radiation" is the same. Rather, the court recognized that radiation effects depend on the type of radiation involved. 193 F.3d at 642-48. Moreover, they argue that, in the Hall case, Judge Ambrose cited TMI in ordering two separate general causation expert disclosure phases, separate pre-trial proceedings and a separate trial (if necessary) for uranium and another, different alpha-emitting radionuclide. Finally, they note that the language cited by Plaintiffs from the insurance litigation related to Hall is taken from the position of the plaintiffs in Hall, not the defendants.

At the hearing, Dr. Hu testified that exposures at the Apollo plant were "non-trivial" and that the Bradford Hill criteria are met if one considers alpha particles, since uranium is an alpha emitter and it is well established that alpha particles cause cell changes that can result in cancers. (Hr'g Day 2 at 57-58, 62-63, 123.) He acknowledged the 14 Royal Society studies, which examined 100,000 nuclear workers and found no death rates above normal expected values for those exposed to uranium, but considered them flawed because internal doses were not calculated. (Hr'g Day 2 at 67-68.) He stated that he is "not sure" he agrees with UNSCEAR's conclusion that there is little or no epidemiological evidence for an association between uranium and any cancer. (Hr'g Day 2 at 77.) He stated that ecological studies (such as those performed by Dr. Boice) are a "crude tool" for estimating exposure, thus they have little use. (Hr'g Day 2 at 128-29.) He stated that the research base is limited and studies have limited statistical power. He indicated that he refers to plutonium (another alpha-emitting radionuclide) by analogy and refers to animal studies. (Hr'g Day 2 at 118-19.) He contended that enriched uranium is more biologically active by weight, and more radiologically active. (Hr'g Day 2 at 119-20.) It is possible to use qualitative estimates of causation if data are inadequate to perform a dose reconstruction. (Hr'g Day 2 at 124-25.) Because uranium travels through the blood and

lymphatic system to every tissue in the body, it can affect every organ. (Hr'g Day 2 at 125-26.) He noted that government programs looked at the studies in concluding that compensation should be paid for various cancers based on uranium exposure. (Hr'g Day 2 at 127.) He stated that there is no "safe" level of exposure to radionuclides. (Hr'g Day 2 at 130-31.)

Dr. Hu testified that he did not look at studies regarding enriched uranium, but that IARC had resolved this question by examining alpha particles, which uranium emits (just as he would have no need to ask if a new brand of cigarettes was carcinogenic). He indicated that, in a book he co-wrote, he stated that he believed nuclear workers were exposed to inhaled uranium , including enriched and highly enriched uranium, but he admitted that 14 studies of 120,000 workers failed to find statistically significant increases in death rates, although he stated that the studies did find some increases so that focusing on one result is misleading. (Hr'g Day 2 at 68-73.) He admitted that UNSCEAR found no correlation between exposed nuclear workers and cancer rates. (Hr'g Day 2 at 75-77.) The workers at Oak Ridge, Tennessee were studied based upon their exposure levels, which were higher than those in Apollo, but the most exposed workers did not show more cancers, although he stated that at least one of these studies was flawed because there were problems with the internal dose assessment. (Hr'g Day 2 at 80-86.) He admitted that there is no consensus in the scientific community (Hr'g Day 2 at 88-90) and that enriched uranium is no more hazardous than normal uranium (Hr'g Day 2 at 93-94). He was asked about a report that was published in 2008 by the Institute of Medicine of the National Academies that evaluated literature for purposes of determining health effects from exposure to depleted uranium (for which he was one of the reviewers) and acknowledged that it found inadequate/insufficient evidence to determine whether an association exists between exposure to uranium and all of the cancers examined. (Hr'g Day 2 at 95-99.) Finally, Dr. Hu was asked

about another case in which he proposed to provide expert testimony (in that case, that exposure to chlorothatlonil can cause chronic headaches) and his testimony was excluded pursuant to Daubert. Although Dr. Hu did not recall that conclusion and had not read the court's opinion, he did not dispute that this occurred. (Hr'g Day 2 at 99-101.)

On "cross-examination," Dr. Hu reviewed how he read the reports describing the types of exposure that likely occurred to residents in the community surrounding the Apollo plant, including soil sampling, how he was most interested in enriched uranium because it is an alpha emitter and is more biologically active than natural uranium. (Hr'g Day 2 at 108-09.) He indicated that many studies are insufficient or flawed because they lack a good measure of internal dose, that uranium worker studies are imprecise because many workers used respirators (and thus would not have inhaled much uranium). (Hr'g Day 2 at 109-10.) He read from a 2013 report that said "no human studies examined the toxicity of enriched uranium and limited number of animal studies on enriched uranium have been conducted." (Hr'g Day 2 at 111.) He explained that in medical science, conclusions must be based on a very high degree of certainty (less than a 5% chance that the association could be random), but this does not mean that one cannot state that exposure to uranium from Apollo could cause cancer. (Hr'g Day 2 at 113-14.) He repeated that, because alpha particles are carcinogenic and uranium emits alpha particles and highly enriched uranium emits more alpha particles, "then the weight of the evidence, in my opinion, even though there's limited epidemiological evidence, is enough to persuade me that more likely than not enriched uranium is carcinogenic in humans." (Hr'g Day 2 at 118.)

Dr. Garabrandt testified that there is a body of scientific literature that is specific to uranium, that Dr. Hu did not utilize the Bradford Hill criteria and did not utilize a scientific

method with respect to uranium. (Hr'g Day 1 at 7, 13-14, 19.)[22] He discussed the fact that 19 studies of uranium workers, which followed more than 150,000 individuals at uranium milling, processing and enrichment facilities over decades of time, found no association between uranium exposure and any specific type of cancer, except that 3 or 4 found a positive association with lung cancer. (Hr'g Day 1 at 15-17.) Dr. Hu did not analyze this body of literature, which Dr. Garabrandt found to be scientifically inappropriate. (Hr'g Day 1 at 17.) In addition, he cited five studies of people who lived near nuclear facilities where uranium was handled and which found no association with cancer. Dr. Hu mentioned only the study concerning Apollo, not the other four. (Hr'g Day 1 at 18-19.) Dr. Garabrandt did apply the nine Bradford Hill criteria and found that, since there was no association between uranium exposure and cancer, the result was that none of the criteria was satisfied. (Hr'g Day 1 at 20-21.)

As did several other witnesses, Dr. Garabrandt testified that uranium, including enriched uranium, is weakly radioactive, that it is very heavy and is absorbed within a millimeter or two of the source, that if soluble it is quickly excreted by the kidneys and that it has a long half-life of hundreds of thousands up to billions of years, such that even if it is retained in the body the amount of radiation a human being is exposed to during his or her lifetime is small. (Hr'g Day 1 at 8-12.) On cross-examination, he was asked about the "concerns" expressed by the Agency for Toxic Substances and Disease Registry (ATSDR) over carcinogenicity of uranium, but he explained that those concerns led to the 19 studies of 150,000 uranium workers, none of which showed an increase in cancer rates. (Hr'g Day 1 at 39.) He admitted that he has testified 119 times as an expert witness over the past several years, primarily for defendants, and earns a

[22] ECF No. 264.

considerable amount of money doing so. (Hr'g Day 1 at 28.) He was asked about IARC's designation of uranium within category 2A, "probably carcinogenic to humans," and he stated that this means "that it does not satisfy the evidence to say that is it known to cause cancer in humans." (Hr'g Day 1 at 31.) He also noted that the agency indicated only "limited" evidence in humans, as opposed to radon-222, for example, for which the evidence was "adequate." (Hr'g Day 1 at 57-58.) Dr. Garabrandt testified that, in science, one must always address contrary reports, in order to distinguish them or to explain why they are in error, and that "there is no justification in the world of science for ignoring reliable evidence." (Hr'g Day 1 at 64.)

Dr. Toohey testified that Dr. Hu's statement that enriched uranium is 70 times more radioactive than normal uranium is not only incorrect, but also irrelevant to the issues in these cases. (Hr'g Day 2 at 17.) He noted that both U-235 and U-238 decay very slowly and are essentially equal on the critical measure of "activity." (Hr'g Day 2 at 18.) He stated that it is scientifically inaccurate to say that all alpha particles are the same: "they have different energies as they come from different sources. And so, the dose is different." (Hr'g Day 2 at 44.) Dr. Mettler testified that the analogy that uranium gives off alpha particles, therefore it causes all cancers, is "just wrong." (Hr'g Day 2 at 174.) On cross-examination, Dr. Mettler was asked many questions about various topics, but he testified that none cast any doubt in his mind that Dr. Hu (and Dr. Melius) had failed to apply proper scientific methodology here. (Hr'g Day 2 at 233.)

Defendants have demonstrated that Dr. Hu's testimony does not survive a challenge under Daubert. His basic approach that "radiation is radiation" is not supported by scientific sources, he cannot name any consensus scientific organizations that agree with him that uranium is a human carcinogen, his hypothesis that uranium causes cancer throughout the body cannot be

tested using the Bradford Hill criteria and he indicated that he did not test his hypothesis that uranium caused each Plaintiff's type of cancer. His failure to apply the Bradford Hill criteria, which he has called the "gold standard" in this field, when he ordinarily does so is significant. See Rimbert v. Eli Lilly & Co., 2009 WL 2208570, at *14 (D.N.M. July 21, 2009) ("That Dr. Jackson chose not to apply the methodology that she personally considers to be the standard in her field to assess causation [Bradford Hill criteria] undermines the reliability of her testimony.") His reliance on an animal study finding "limited" evidence linking uranium to cancer when human studies show the evidence is "inadequate" does not meet the "fit" requirement. See Paoli, 35 F.3d at 743 (noting that "animal studies may be methodologically acceptable to show that chemical X increases the risk of cancer in animals, but they may not be methodologically acceptable to show that chemical X increases the risk of cancer in humans."). He "appears willing to base a causation conclusion on any study that demonstrates an association between any type of ionizing radiation and a particular cancer, yet disregards the available epidemiological evidence specific to uranium that fails to support a causal link." Cano, 362 F. Supp. 2d at 851. In addition, because IARC has found that the degree of evidence of carcinogenicity of uranium and its decay products, inhalation of ore dust containing uranium-234, uranium-235 and uranium-238 is "limited" in animals and "inadequate" in humans, it is unreasonable for Dr. Hu to rely on more general statements in the paper that "internalized radionuclides that emit alpha particles and beta particles are carcinogenic to humans" to support a conclusion that natural uranium exposure caused cancer in these Plaintiffs. Id. at 852. And Dr. Hu's criticisms of multiple studies finding no link between cancer and exposure to uranium by miners does not support the contrary proposition. Therefore, the motion to exclude his testimony pursuant to Daubert should be granted.

James Melius, M.D., DRPH

Dr. Melius, a physician and Doctor of Public Health, is Plaintiffs' sole specific causation expert. He currently serves as Chair of the federal Advisory Board on Radiation and Worker Health which provides oversight on the federal program to compensate former Department of Energy nuclear facility workers who have developed cancer, and as Chair of the Steering Committee of the World Trade Center Responder Medical Programs which advises the federal government on the federal medical programs for rescue and recovery workers who were exposed at the World Trade Center subsequent to the terrorist attacks in 2001. He offers the opinion that, with respect to each of the 75 Plaintiffs, release of uranium from the Apollo plant was a "substantial contributing factor" to that individual's cancer. He states that he relies upon "differential diagnosis," a technique in which certain causes are "ruled in" and then "ruled out," leaving the remaining cause as cancer in each instance. (Melius Rpt. at 2-4.)[23]

Defendants contend that his methodology lacks the hallmarks of true differential diagnosis and does not comply with Third Circuit standards in the following respects: 1) Dr. Melius has no information as to each Plaintiff's dose, the maximum or minimum amount to which the person was exposed, and he relied for his conclusions on the opinion of Dr. Hu, but Dr. Hu did not assess the level of impact of uranium; 2) Dr. Melius did not rule out possible alternative causes, such as natural background radiation, smoking and obesity; 3) he failed to employ standard medical diagnostic techniques, such as physical examinations and lab tests; 4) he was haphazard in applying his methodology (he used a 1½ mile radius around the plant, but sometimes exceeded it); and 5) his opinions are untestable.

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[23] Milburn Decl. (ECF No. 219) Ex. I.

Dr. Melius acknowledged that his causation opinions are not based on any Plaintiff's alleged radiation dose from the Apollo facility. (Melius Dep. I at 105:15-108:5.)[24] Not only did Dr. Melius lack any maximum estimate, he had no minimum estimate either – no "floor dose" of the type he was provided in the Hall litigation. Id. at 166:22-24; Melius Dep. III at 227:4-19.[25] He relied on Plaintiffs' other experts – Franke, Dr. Ring and Dr. Ketterer – for the conclusion that "substantial," "significant" amounts of radionuclides had been released into the Apollo area, and proceeded himself to conclude that each of the 75 Plaintiffs had consequently been exposed to "substantial," "significant" radiation. (Melius Dep. III at 225:7-226:6; Melius Dep. IV[26] at 439:24-441:4.) By "significant" or "substantial," however, Dr. Melius means any amount of radiation from the facility. (Melius Dep. IV at 441:5-16; Melius Dep. I at 167:6-22.) That could include minute exposures below 40 millirems or possibly even below 1 millirem. (Melius Dep. IV at 441:17-443:17, 495:9-497:25; Melius Dep. I at 299:3-15.) He has no opinion that any Plaintiff's dose of radiation from facility emissions was more than the dose that Plaintiff received each year from natural background – cosmic rays, terrestrial sources, radon and internal radionuclides affecting everyone. (Melius Dep. I at 297:9-299:15.)

Defendants note that Dr. Melius relied upon the general causation opinion of Dr. Hu that inhaled uranium is capable of inducing each and every type of cancer. (Melius Dep. I at 209:25-211:23.3.) But he did not evaluate the epidemiologic literature bearing on the strength of the link between uranium and the types of cancer diagnosed in plaintiffs. He could cite to no evidence from the extensive body of uranium epidemiologic studies that supports the conclusion that

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[24] ECF No. 219 Ex. A.
[25] ECF No. 219 Ex. C.
[26] ECF No. 219 Ex. D.

uranium exposure has a strong impact, a moderate impact, or even a detectable impact in causing the various cancers at issue. With respect to the studies of individuals exposed to different types of radiation, not involving uranium, Dr. Melius also could not cite to evidence reporting even a detectable increase in cancer at low doses, below about 5,000-10,000 millirems. (Melius Dep. III at 218:3-220:25; Melius Dep. IV at 471:1-18; see Melius Dep. III at 52:23-53:9, 57:22-58:2, 107:11-109:17, 155:1-21, 172:8-173:2, 186:21-187:17, 204:25-205:08, 238:2-10, 258:12-16, 279:16-19; Melius Dep. IV at 295:10-14, 309:7-11, 312:8-17.) Thus, Dr. Melius had no basis in the studies to infer that plaintiffs' risk from facility exposure was "substantial" in comparison either to other established risk factors or to the background incidence of cancer from unexplained causes.

Dr. Garabrandt states that Dr. Melius failed to perform all of the steps that are essential in establishing that exposure to uranium caused the Plaintiffs' cancers, specifically: Dr. Melius failed to show that the Plaintiffs were exposed to uranium under circumstances that are known to place them at a significantly increased risk of cancer; Dr. Melius presents no objective support whatsoever for his conclusion that plaintiffs' exposure to uranium was "substantial" or "significant"; Dr. Melius has no opinion as to the levels of uranium, or the levels of ionizing radiation associated with uranium, to which Plaintiffs were exposed; Dr. Melius failed to adequately consider alternative causes of Plaintiffs' cancer, an essential element in establishing causation and although he acknowledged alternative risk factors, he provided no basis for ruling out the possibility that such factors contributed to the Plaintiffs' cancers independently of any contribution from uranium exposures; and he failed to follow established guidelines for attributing cancers to ionizing radiation. (Garabrandt Decl. ¶ 15.)

In his declaration, Dr. Mettler states that:

> I have reviewed the report and opinions of plaintiffs' expert Dr. James Melius. Dr. Melius opines that each of the plaintiffs' claimed exposure to uranium and "other radioactive materials" from the Apollo facility "made a significant contribution" to the development of his or her cancer. Dr. Melius' causation opinions lack any medical or scientific basis. He acknowledges that he has not estimated a dose (whether minimum or otherwise) to any plaintiff from exposure to uranium from the Apollo facility. He acknowledges that he is unaware whether the plaintiffs' doses of radiation from the facility exceeded background radiation doses received by the general population, from smoking (for certain plaintiffs), or radiation doses that the plaintiffs received from diagnostic medical procedures. Because the risk of cancer from ionizing radiation is dose-dependent, and because the risk for any type of cancer is minimal or negligible at very low doses, it is not medically or scientifically justified to attribute cancer to radiation doses that are either not above annual background doses or above certain levels discussed earlier in my report. Dr. Melius also ignores or fails to adequately consider other risk factors such as smoking, diet, and family history of cancer which likely contributed to the development of plaintiffs' cancers independent of any potential uranium exposure.

(Mettler Decl. ¶ 11.)

Plaintiffs respond that Dr. Melius' differential diagnosis methodology was found admissible in the Hall case and there is no reason to revisit Judge Ambrose's decision. They further contend that Daubert does not require certainty and Dr. Melius considered risks based on general causation data from Dr. Hu and epidemiological studies concerning ionizing radiation, and ruled out other risk factors (as did Defendants' experts). Plaintiffs argue that, according to the TMI case, the issue is ionizing radiation, not uranium specifically, and Dr. Melius cited the Apollo-Parks Cancer Incidence Study of 1984-92 from the PDH, as well as numerous other sources (Franke, Ketterer, Ring, Hu, NIOSH) to determine that there was significant ionizing radiation exposure. He also looked at medical records, questionnaires, affidavits, depositions of Plaintiffs and survivors. The Court of Appeals has never held that medical experts have to testify using dose-response relationships and it is not necessary to rule out every other potential cause of cancer. Moreover, one cannot rule out "idiopathic" causes because the word idiopathic

means "unknown" and thus this would be impossible. The Court of Appeals has held that, if a cause is unknown, it is sufficient to refer to a defendant's conduct having increased the risk, no degree of risk is sufficient and the expert's opinion need not be stated with any particular degree of certainty. Finally, they contend that Dr. Melius' methodology meets the admissibility test and that his credibility is a matter for the jury to determine.

In their reply brief, Defendants reiterate that Dr. Melius concluded that all Plaintiffs had "significant" exposure without defining that term, argue that Plaintiffs misread TMI and ignore its dictate regarding epidemiological studies and contend that Dr. Melius did not "rule out" any other causes. They contend that, in the Hall case, Dr. Melius had dose data, but here he does not; and the Hall case preceded the TMI court's holding that epidemiological studies are necessary to establish causation.

At the hearing, Dr. Melius (called by Defendants as a hostile witness) testified that, although all Americans are exposed to hundreds of millirems of ionizing radiation every day, adding up to thousands of millirems over the years, he believes Plaintiffs received "substantially" more than background radiation, yet he could not quantify this amount. (Hr'g Day 1 at 67-69.) He considers the medical radiation they received (x-rays, CT scans, etc.) to be part of the background radiation. (Hr'g Day 1 at 70-73.) He admitted that radon emissions could add up to as much as 200 millirems per year, but he stated that he did not consider radon to be the cause of Plaintiffs' cancers; it was also considered part of the background. (Hr'g Day 1 at 74-75.) He indicated that he considered if women had taken oral contraceptives, but if the dose was low he discounted it, and he did the same with smoking (if Plaintiffs smoked only a little, or if they quit 10 to 15 years before their cancers appeared, he discounted smoking as a cause). (Hr'g Day 1 at 76-81.) He did not know of any studies liking uranium to cancer risk, but he claimed that studies

showing no such link were flawed. (Hr'g Day 1 at 87.) He indicated that he reviewed the Plaintiffs' questionnaires and, for the most recently added Plaintiffs, he concluded that the fact that they had lived within 1.5 miles of the Apollo plant was sufficient. (Hr'g Day 1 at 89-92.) When asked if he had found any risk factor sufficient to overrule causation of uranium, he said he had not, but posited the hypothetical of an individual who had been exposed to asbestos and had developed mesothelioma. (Hr'g Day 1 at 94-95.) For all 75 Plaintiffs, he found the following factors not substantial: family history, work history (except working at the Apollo plant) and obesity (except for one person). (Hr'g Day 1 at 101-02.) He admitted that he did not independently evaluate emissions from Apollo, but instead relied on experts who opined that there was not enough data to evaluate. (Hr'g Day 1 at 114.) He admitted that he was not an expert in dosimetry or health physics.[27] (Hr'g Day 1 at 116.)

On "cross-examination" by Plaintiffs' counsel, Dr. Melius indicated that in the nuclear radiation safety field, uranium is generally understood to be carcinogenic. (Hr'g Day 1 at 122.) He stated that the general consensus is that ionizing radiation causes cancer and there is no known "safe" level of exposure, which he referred to as the linear no-threshold model. (Hr'g Day 1 at 125-29.) He explained that he has used the differential diagnosis methodology in other cases, including Hall, without being excluded. (Hr'g Day 1 at 131-32.) He stated that he had reviewed residential and work histories, medical records and interviews and concluded that no other factors were the sole cause of Plaintiffs' cancers. (Hr'g Day 1 at 132-36.) He relied on the expert reports of Dr. Hu, Dr. Ring, Franke, Dr. Ketterer (for soil samples) and Oak Ridge Associated University (ORAU) reports. (Hr'g Day 1 at 139-40.) He admitted that the did not

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[27] "Health physics is the name given to the study of problems related to the protection of man from exposure to radiation." TMI, 193 F.3d at 680 n.110 (citation omitted).

have the data to link the amount of exposure to ionizing radiation to cancer but stated that he did need it to make estimates, which are commonly accepted in the medical/scientific community. He performed a qualitative analysis, as there was not enough data to perform a quantitative one. (Hr'g Day 1 at 141-42.) He explained that the 1.5 mile radius from the plant was based upon soil samples and was consistent with air movement—the amount of uranium drops off considerably beyond that point. (Hr'g Day 1 at 147.) He indicated that the plant closed in the early 1980s and that he utilized accidental releases of uranium either as documented or estimated and also relied on "general releases." (Hr'g Day 1 at 148.)

On further questioning from defense counsel, Dr. Melius acknowledged that, in the Hall case, he had epidemiology and dose data for the 8 sample plaintiffs (based on a report by Dr. Thorne), but in this case he has no minimum or maximum estimate, and that since the Hall cases his estimates of increased cancers in Apollo have been questioned (although he does not agree with this criticism). (Hr'g Day 1 at 156-58.) He stated that Dr. Hu looked at the epidemiology here. Finally, he testified that he had excluded one person who developed lung cancer and two people who had non-melanoma skin cancer. (Hr'g Day 1 at 160-62.)

In his testimony, Dr. Garabrandt criticized Dr. Melius for not failing to apply the five steps used to determine specific causation, for not considering dose, for making no reference to published literature, for failing to consider alternative causes (he mentioned them but simply dismissed them) and for relying solely on whether the person lived within 1½ miles of the Apollo plant. (Hr'g Day 1 at 22-26.) Dr. Toohey observed that Dr. Melius failed to calculate dose, and he failed to calculate background radiation, although doing so is not difficult, as there is a simple formula for estimating it. (Hr'g Day 2 at 14.) He stated that when Dr. Melius stated that exposure was "substantial" or "significant," despite the lack of dose opinions from Dr. Ring

or Franke, "his estimate is purely subjective and it's not informative because there's no quantification involved." (Hr'g Day 2 at 14-15.) There is no way to test Dr. Melius's methodology and no way to peer review the conclusions he has reached. (Hr'g Day 2 at 15.) He noted that Dr. Till, an expert in environmental dose reconstruction, had applied a well-published (by the NCRP and others) 6-step formula to calculate radiation for these cases. (Hr'g Day 2 at 21-23.) Dr. Melius did not apply this methodology and is not an expert in any of the fields needed to do an environmental dose reconstruction, namely: nuclear engineering, radioecology, uranium processing, stack design, vent design, monitoring systems, environmental transport models, wind data, and soil sampling. (Hr'g Day 2 at 24.)

On cross-examination, Dr. Toohey rejected Plaintiffs' counsel's suggestion that there is point at which the level of uncertainty is so high that the calculation cannot be made. (Hr'g Day 2 at 25-26.) Dr. Toohey testified that Dr. Melius did not use any recognized scientific method and that his results cannot be tested or peer reviewed. He observed that Plaintiffs' experts appear to be focusing on the concept of "mass"(the physical amount of material present, which is important for chemical toxicity) but the issue is "activity" (radiation decay rate) for purposes of calculating radiation dose calculations, which is the crucial matter. (Hr'g Day 2 at 16.)

Defendants called Dr. Stanley Marks, Chairman of the UPMC Cancer Center in Pittsburgh, chief medical officer, director of clinical services and director of hematology oncology at Shadyside Hospital, who testified that most cancers cannot be traced back to a specific cause, other than lung cancer (linked to smoking) and a few genetic mutations. (Hr'g Day 2 at 133, 135-37.) Dr. Marks criticized Dr. Melius for having claimed to have applied differential diagnosis (which Dr. Marks stated is used by physicians to identify symptoms, not to determine the cause of a disease), but yet failed to rule out obvious alternatives. (Hr'g Day 2 at

139-40.) He provided three examples: 1) an 82-year old woman with chronic lymphocytic leukemia, but even though age is a major factor for this cancer, Dr. Melius ignored this factor (Hr'g Day 2 at 140-42); 2) a 52-year old woman with acute myelogenous leukemia, but she had a history of smoking (which is known to be a factor for this cancer) and had worked at a laundry company that may have used benzene (which is also known to be a carcinogen), yet Dr. Melius ignored these factors (Hr'g Day 2 at 142-44); and 3) a 40-year old woman with an aggressive type of breast cancer, but she had a family history of cancer (her mother and several cousins had cancer; she refused to be tested for the genetic mutation) and had taken birth control pills for many years (a known factor for increasing cancer risk), yet Dr. Melius discounted all of these factors in favor of finding uranium exposure from the Apollo plant (Hr'g Day 2 at 144-46). Dr. Marks concluded that it was not medically valid for Dr. Melius to attribute every one of the cancers alleged by the Plaintiffs to uranium exposure from the Apollo plant. (Hr'g Day 2 at 147.)

On cross-examination, Dr. Marks stated that in his own practice, he had never seen a case where cancer was attributed to uranium exposure. (Hr'g Day 2 at 148.) It was pointed out to him that he never attributed "causes" to cancers, only risk factors, even in the example of someone who smoked heavily for many years and developed lung cancer. (Hr'g Day 2 at 152-56.)

Dr. Mettler testified that background radiation does not include medical procedures and that it was not valid for Dr. Melius to offer causation or risk assessments without a calculation of the dose Plaintiffs received. (Hr'g Day 2 at 193-96.)

In the Cano case, 53 plaintiffs with various cancers brought suit against a uranium mining company, claiming exposure to uranium ore had caused their cancers. The defendants brought a

Daubert challenge against their specific causation expert, Dr. Malin Dollinger, who claimed to have utilized differential diagnosis. The court first noted that Dr. Dollinger used a linear no-threshold model based on any source of ionizing radiation and said that every possible cause (including background radiation) was also a but-for cause. 362 F. Supp. 2d at 842-46. The court stated that Dr. Dollinger's methodology was not differential diagnosis as applied by physicians to diagnose a patient because he did not rule causes in and out, but rather it assumed that all potential causes were actual ones. In addition, his methodology could not be tested, he had never published it and it had no general acceptance in the medical and scientific communities. Id. at 846-47. He continually asserted that "dose does not matter," a statement that is simply wrong in science and under the law. Id. at 847-48.

The court noted that some courts have rejected the linear no-threshold model in litigation altogether, but even those that allow it (such as the Third Circuit in TMI) require epidemiological studies to prove causation. Id. at 849-50. The court also found Dr. Dollinger's method unreliable; for example, he used a report that found an increase in bladder cancer but ignored that same report's finding of no increase in breast cancer. Id. at 850. The court criticized Dr. Dollinger for relying on "general" statements about radionuclides while ignoring the 1994 UNSCEAR Report on uranium miners (which found no hazards other than with respect to lung cancer), the 2001 IARC Monograph (finding evidence "limited" in animals and "inadequate" in humans), the Royal Society Studies (finding only an increase in lung cancer, which it connected to radon inhalation by uranium miners) and the BEIR VI Report (reporting similar findings). The court also concluded that Dr. Dollinger failed to distinguish studies with different doses and types of radiation. Id. at 851-53.

The court held that Dr. Dollinger cited exposure by parents to explain cancers in 4

children plaintiffs, but no study supported such causation in humans and a study of the Japanese atomic bomb survivors found no increase in cancer rates among the children of survivors. Id. at 854-57. Finally, the court observed that Dr. Dollinger had taken an average dose from a range by Dr. Resnikoff but admitted that it could be wrong, and he compared annual background exposure (250 millirems) to cumulative organ doses over decades (1,000 millirems), or as the court put it, apples to oranges. Id. at 858.

Many of the criticisms noted by the court with respect to Dr. Dollinger are equally applicable to Dr. Melius in these cases. The Court should reject Defendants' attempt to discard the linear no-threshold model, as it is approved within the Third Circuit. Nevertheless, Dr. Melius cites to no epidemiological studies to prove causation. He calls his method differential diagnosis, yet he fails to explain why he did not rule out smoking, obesity, genetic factors, benzene exposure, radon and many other possible and obvious alternative causes in order to conclude in each instance that uranium is the cause of the individual's cancer. He appears to rely solely on the fact that the Plaintiffs lived or worked within 1.5 miles of the Apollo facility, but this method has not been published and has not been generally accepted in the medical and scientific communities. He has not explained how his method can be tested.

Plaintiffs contend that the Cano case was decided under Texas law and thus is not relevant to this Court, which must decide these cases consistent with Pennsylvania law. However, their contention does not withstand scrutiny. Although the Cano decision opens with explanations of the standards under Texas and federal law, the actual grounds on which Dr. Dollinger's testimony were excluded are not specific to any jurisdiction.

As Judge Fischer recently observed, "when an expert fails to rule out obvious alternative causes, or even consider them … he is prevented from considering whether the alternative cause

is the sole cause of the injury, thereby undermining his entire medical causation opinion." Pritchard v. Dow Agro Sciences, 705 F. Supp. 2d 471, 495 (W.D. Pa. 2010), aff'd mem., 430 F. App'x 102 (3d Cir.), cert. denied, 132 S.Ct. 508 (2011). Dr. Melius, like the expert in Pritchard, fails to rule out obvious alternative causes.

Defendants have demonstrated that Dr. Melius's testimony does not survive the Daubert challenge: he has no information as to each Plaintiff's dose (contrary to the situation in the Hall case when he had such information)[28] or the maximum or minimum amount to which the person was exposed, and he relied for his conclusions on the opinion of Dr. Hu, but Dr. Hu did not assess the level of impact of uranium; he cites to no epidemiological studies to support his conclusions; he does not rule out possible and obvious alternative causes, such as natural background radiation, smoking, radon and obesity (yet paradoxically, he rules out oral contraceptive use if the dose was small and smoking if the person quit 10-15 years ago, thereby taking dose into account); his method has not been published and has not been generally accepted in the medical and scientific communities; and his opinions are untestable. Therefore, the motion to exclude his testimony should be granted.

John E. Till, Ph.D.[29]

Dr. Till has a Ph.D. in nuclear engineering and is the president of Risk Assessment Corporation (RAC). He calculated a source term for the Apollo facility; conducted an extensive review of the depositions, questionnaires and medical and employment documents for each Plaintiff to compile information about where each person lived, worked and went to school and

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[28] Judge Ambrose indicated that "Dr. Melius evaluated the exposure of each Plaintiff by reference to the dose estimate provided by Plaintiffs' dose experts." (ECF No. 240 Ex. A at 21.)
[29] Plaintiffs' challenge to Dr. Till is based solely on the record; no testimony was presented by him at the hearing.

how much time was spent at each location during the years of the Apollo facility's operation; prepared a model of the Apollo environment in order to model air dispersion of uranium in the relevant areas; and used ICRP models to calculate individual exposure assessments and resulting organ-specific doses for each Plaintiff. (Till Report, Chs. 4, 7, 8.)[30] The total doses range from .002 millirem to a maximum of 1543 millirems, and most of them are at the lower end of the scale. (Till Report Ch. 8.) Moreover, the individual who received 1543 millirems from uranium (and developed lung cancer) was a 2-pack-a-day smoker who also likely received a total of 36,000 millirems from smoking and 153,900 millirems from radon over the same time period. (Till Rpt. Ch. 10 at Table 10-7.) "Radon is the largest contributor to terrestrial radiation because people spend most of their time indoors." TMI, 193 F.3d at 646. The court noted that radon "is responsible for more than half of the natural radiation we are exposed to, i.e., 1.3 mSv per year or 130 mrems per year." Id. at 646 n.57.

Plaintiffs contend that Dr. Till failed to use reliable methodology in recreating the Apollo facility's source term, correlating airborne emissions of enriched uranium with production data from the plant because the facility failed to monitor its stack emissions and the neighboring environment. Plaintiffs observe that, in the Hall case, Dr. Roger Mattson (B&W's own source term expert) criticized this very assumption and, in the TMI case, the Court of Appeals excluded expert testimony on similar grounds. In addition, they argue that the intentional failure to monitor and preserve adequate data cannot be used to Defendants' advantage to claim there is not enough data to reach a result.

Defendants respond that Dr. Till relied upon the well-accepted science of historical dose

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[30] Phillips Decl. (ECF No. 237) Ex. A.

reconstruction to prepare source term and dose reconstruction estimates, a method he has applied at least 8 times over the past 25 years (and he has never been excluded under Daubert). See In re Hanford Nuclear Reservation Litig., 2009 WL 1587907, at *2 (E.D. Wash. June 3, 2009); Cook v. Rockwell Int'l Corp., 580 F. Supp. 2d 1071, 1173 (D. Colo. 2006). They note that his research and methodologies have been peer-reviewed and evaluated by independent scientific agencies such as the National Academy of Sciences and the Colorado Department of Public Health and Environment. (Till Rpt. App. A at A-13 to A-19.) His work has been cited by the NCRP as an example of how to perform a scientifically valid dose reconstruction. (ECF No. 237 Ex. B.) Plaintiffs are actually challenging Dr. Till's conclusions, but that argument goes to the issue of weight (to be determined by the jury), not admissibility. Dr. Till properly calculated average release over a year, not sporadic ones, and compared to other risks (smoking, radon) to reach his conclusions about exposure. Dr. Mattson did not have the benefit of advantages in technology and computer search techniques in 1998 and Dr. Till's source term has been tested and proven by comparison to actual data from Apollo. Plaintiffs make no prejudice argument under Rule 403 and thus there is no basis to exclude his testimony. Finally, they argue that the fact that data is missing does not exclude proper extrapolation from existing data and can be challenged on cross-examination.

In their reply brief, Plaintiffs contend that Dr. Till could not defend his methodology at his deposition, that he could not answer basic questions about his methodology and the assumptions he relied upon and that Defendants failed to offer any explanation or defense to any problems cited.

First, Dr. Till's source term re-creation is based entirely upon the proposition that emissions from the Apollo facility are correlated with receipts as a proxy for production at the

facility. (Till Dep. at 85:21-86:7; 127:9-15.1.)[31] However, Dr. Mattson reported that effluents went down when production went up. (Mattson Dep. Dated 3/31/1998 at 80-81.)[32] Dr. Till disagreed with this assessment. (Till Rpt. at 117.)

Plaintiffs note that Dr. Till read Dr. Mattson's expert report before selecting his methodology in this case. (Till Dep. at 99:17-21.) Dr. Till further admitted that he also read the deposition of Dr. Mattson, which included the statements regarding the lack of direct correlation between emissions and production. (Till Dep. at 30:11-13.) In his deposition, Dr. Till recognized if there were no correlation between production and release rate, this model of recreating source term from receipts would not be reliable. (Till Dep. at 74:3-9.) However, despite knowing this major limitation of his model and the associated claim of Dr. Mattson, Dr. Till chose to utilize this flawed methodology anyway. Dr. Till could not offer any testimony that he (or anyone else on his team) verified the central assumption that emissions were correlated with production (via proxy of receipt data). (Till Dep. at 127:19-128:5.) Dr. Till was unable to defend his own assumptions or even criticize the conclusions of Mattson. When asked if he agreed with Mattson, Till stated he could not "[b]ecause I don't know in what context he's making this statement." (Till Dep. at 118:3-4.)

Dr. Till testified that his decision to model his source term estimate on the relationship between releases and production was based upon his experience at other facilities. Id. However, Dr. Mattson explained that this method, which was true elsewhere, was not true for Apollo. (Mattson Dep. at 78-81.)[33]

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[31] Pls.' Reply Br. (ECF No. 257) Ex. A.
[32] ECF No. 257 Ex. B.
[33] ECF No. 257 Ex. C.

Plaintiffs argue that according to the record, Dr. Mattson reviewed twice as many pages as Dr. Till and conducted a review of data that would have required more than computer search terms in 1998. (Till Dep. at 118-122.) Moreover, Dr. Mattson had access to classified data to which Till never sought access. (Till Dep. at 118-22.)

Dr. Till claims that the air monitoring data and soil sampling data confirm his overall work. (Till Dep. at 162:14-18.) However, Plaintiffs argue that Dr. Till's analysis of the air monitoring data and soil sampling data each suffer from their own significant methodological flaws.

In his deposition, Dr. Till testified that environmental monitoring data was used to verify his opinions. (Till Dep. at 164:19-24.) Moreover, Dr. Till testified that if information was not captured in the monitoring data, it was not used to verify his opinions. Id.

Additionally, Dr. Till was aware that the Apollo facility released both soluble and insoluble uranium. Despite this, Dr. Till never confirmed that both types of releases would be captured by the effluent monitoring systems. (Till Dep. at 162-63.) In fact, according to the 1985 audit of the Portsmouth uranium enrichment facility, soluble uranium cannot be accurately measured by the types of monitors present at the Apollo facility. See Franke Rpt. at 15 (ECF No. 237 Ex. D.) Thus, Dr. Till's environmental monitoring data cannot be used to validate his central assumption about the correlation between production and releases.

Next, Dr. Till used soil data obtained from Plaintiffs' expert Dr. Ketterer in an attempt to support his opinions. However, Dr. Till calculated uranium concentration per unit of activity, something that Dr. Ketterer never provided in his report. (Till Dep. at 174:16-24.) When asked about the specific method he used to calculate his dataset, Dr. Till was unable to provide information relative to the formula he used or what assumptions he made during the calculation.

(Till Dep. at 175:7-9.) Because Dr. Till was unable to provide the equations that he used or the assumptions that went into the soil calculations, this method of confirming his opinions must be deemed unreliable as well and fail as well.

Plaintiffs contend that, while Dr. Till's central assumption, that production (via the proxy of receipt data) is correlated with releases from the Apollo plant, it is fundamentally flawed; the manner in which he calculated annual receipt data is equally flawed. In his report, Dr. Till utilized annual receipt data for the Apollo facility. (Till Dep. at 138-139.) However, the data that the facility maintained was kept in fiscal year. Id. In order to utilize this data, Dr. Till had to convert it from fiscal year to calendar year. Id. Plaintiffs note that Dr. Till did not use any scientific or accounting methodology to correlate the timing of the shipment receipts with the appropriate calendar year. (Till Dep. at 139:4-8.) Instead, Dr. Till simply divided the fiscal year in half and attributed equal amounts to each of the calendar years that made up the fiscal year. Id. The obvious flaw in this method is that it assumed even distribution of receipts throughout the year. (Till Dep. at 139:17-19.) Dr. Till testified he had no support for the use of this methodology. (Till Dep. at 146:17-22.)

Plaintiffs contend that a second major flaw with Dr. Till's work is found in his recreation of the 1963 vault fire and release of uranium from the Apollo facility. Instead of applying the valuable and commonly used mathematical formula found in the Department of Energy Handbook, which he cites as a source, Dr. Till used an unspecified formula to recreate the event. (Till Dep. at 194-95.) Dr. Till could not provide such basic information about the formula as its terms, the source of the formula, or whether it has been peer reviewed. (Till Dep. at 200.) Because Dr. Till has not been able to identify any of this information, it cannot be considered reliable under Rule 702.

Finally, Plaintiffs argue that Dr. Till utilized an inappropriate airborne dispersion modeling program called CALPUFF. (Till Dep. at 224.) However, according to the EPA, CALPUFF is not appropriate for short-range dispersal modeling except in specific limited circumstances, not applicable in the instant actions. (Till Dep. at 224-42; ECF No. 257 Ex. E.) According to the EPA, CALPUFF understates exposure in short range applications. Moreover, there is little validation or peer review of the model for short range applications. In his deposition, Dr. Till could provide no justification for his use of the CALPUFF model. He offered no peer reviewed support for CALPUFF's use in applications like this. In fact, Dr. Till did not know if CALPUFF had ever been validated at distances less than 2.5 km. (Till Dep. at 224.) Moreover, he offered no independent validation of the model. Id. Plaintiffs note that Atlantic Richfield, in responding to the motion to exclude Whipple and Hayes, observed that AERMOD (not CALPUFF) is the recommended EPA model for transport distances up to 50 km. (ECF No. 233 at 5; ECF No. 234 Ex. A ¶ 112, Ex. D.) Thus, they argue that, because CALPUFF is inappropriate in applications like this, Dr. Till's opinions are unreliable.

In a public liability action, a defendant's liability depends upon whether it released radiation in excess of 10 C.F.R. § 20.106 averaged over a year. TMI, 67 F.3d at 1119. Dr. Till's source term opinions indicate that, despite the isolated incidents Plaintiffs cite, Defendants did not exceed these limits. Moreover, both the National Research Council's 1995 report and the NCRP demonstrate that extrapolating from existing data to fill in gaps, as Dr. Till did, is an approved scientific technique. (ECF No. 237 Ex. C at 20, 24.) As the Court of Appeals has observed, "Daubert neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance. It demands only that the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and

methodologically reliable fashion." United States v. Mitchell, 365 F.3d 215, 244 (3d Cir. 2004) (citation omitted). Thus, the fact that the EPA recommends an airborne dispersion model other than CALPUFF for certain situations does not, in and of itself, mean that Dr. Till's decision to employ CALPUFF here renders his testimony inadmissible.

Plaintiffs have not demonstrated that Dr. Till's testimony should be excluded under Daubert. The alleged deficiencies in Dr. Till's methodology would properly be the focus of cross-examination at trial, but do not demonstrate that his testimony should be excluded. Therefore, the motion to exclude his expert testimony should be denied.

Christopher Whipple and Stanley Hayes[34]

Dr. Whipple is a principal with Environ International Corporation. He holds an M.S. and Ph.D. in engineering science. Stanley Hayes is also a principal with Environ. He holds an M.S. degree in aeronautics and astronautics. Environ's report states their opinions that:

> 1) Airborne releases of uranium from the Apollo Facility were within permitted regulatory limits. Annual average uranium activity concentrations did not exceed the AEC/NRC's annual average maximum permissible concentration ("MPC") of 8.8 dpm/$m^3$ for insoluble uranium or 44 dpm/$m^3$ for soluble uranium.
>
> a. Annual average concentrations measured by roof edge monitors beginning in 1966 did not exceed the MPC.
>
> b. Annual average concentrations measured by ambient air monitors beginning in 1966, both on- and off-site, did not exceed the MPC, and off-site measurements were a number of times lower than measurements at the roof edges.
>
> c. Based upon AEC and NRC statements, production levels, stack records, soil sampling data, operational factors, and other records, there is no evidence that annual average concentrations exceeded the MPC prior to

[34] Plaintiffs' challenge to Whipple and Hayes is based solely on the record; no testimony by them was provided at the hearing.

1966.

2) Air, soil, fallout, and radiological activity levels decreased rapidly with distance from the Apollo Facility, with the highest levels in the immediate proximity of the facility and mostly on site.

a. Air levels measured at the Apollo Office, just across the street and less than 100 meters from the facility, were a number of times lower than levels on the facility site or at its roof edges, and were lower still at air monitors further away.

b. No offsite soil samples exceeded the NRC soil cleanup concentration of 30 pCi/g uranium. This concentration was set by the NRC as the level below which the site could be released for unrestricted use.

c. Uranium activity in soil samples is above natural background only within about 300 – 400 meters of the facility.

d. Fallout data show an order-of-magnitude (ten times) decrease in uranium concentrations between the facility rooftop and the Apollo Office, just across the street from the facility.

e. Radiological survey data show that the highest measured activity levels were onsite.

3) Hypothetical bounding dose estimates that overstate actual Plaintiff doses are fractions of natural background.

4) Dispersion modeling demonstrates that uranium concentrations diluted rapidly in the air with increasing distance from the Apollo Facility.

5) Dose estimates adjusted for dilution due to air dispersion are even lower and further below natural background.

6) Estimates of Plaintiff doses are robust and insensitive to uncertainties.

(Whipple & Hayes Expert Report at 3-4.)[35]

Plaintiffs contend that Whipple and Hayes do not rely on sound scientific methodology in recreating the airborne concentration of radionuclides outside the Apollo facility, they fail to rely

[35] Milburn Decl. (ECF No. 234) Ex. A.

on actual monitoring because the plant regularly failed to monitor its stack emissions and environment and their estimates are at odds with the factual record. They argue again that the failure to monitor cannot be used to Defendants' advantage, as annual reports were not required and submitted until 1977.

Defendants respond that the Environ methodology is reliable and will aid the trier of fact in these cases. Much of Plaintiffs' challenge is focused on Dr. Till's methodology, but Environ did not offer estimates of Dr. Till as to the vent, stack and incinerator emissions which comprise the "source term." Rather, Environ measured ambient air monitoring data to determine radionuclide concentrations in the area around the Apollo facility. Using these concentrations and standard air dispersion modeling, Environ calculated the amount of radionuclides available for inhalation and resulting organ doses to Plaintiffs. For early years before ambient air monitors were in operation, Environ relied upon Franke (one of Plaintiffs' experts) for estimates. Plaintiffs' reliance on internal memos of isolated releases is irrelevant because the NRC indicates that, with respect to radionuclide releases, the annual average of air concentrations in unrestricted areas should not exceed the MPC. Finally, they observe that there would be no basis for a Rule 403 exclusion of Whipple and Hayes because the issue of prejudice is not even raised.

Plaintiff did not submit a reply brief with respect to Whipple and Hayes. Plaintiffs have failed to demonstrate that the methodology employed by Whipple and Hayes should be excluded under Daubert. Not only did they rely on Franke's data to fill in missing estimates, but their sampling of air data utilized a method approved by the EPA (ironically, the very method Plaintiffs criticize Dr. Till for not using). Employing air concentration data to calculate inhalation dose is an accepted scientific technique recommended by the EPA and radiation dose reconstruction authorities. (ECF No. 234 Ex. F at 19, 50-51; Ex. G at 29.) Isolated incidents of

emissions that exceeded federal standards does not demonstrate that the regulations, which address annual averages, were violated. Neither AEC nor NRC found the facility's airborne releases to unrestricted areas to be in violation of 10 C.F.R part 20 for the period of 1957-1978. (Knapp Rpt. at 13-17; Kalt Rpt. ¶¶ 53-60, 68-72.)[36] Their testimony would aid the trier of fact. Therefore, with respect to Whipple and Hayes, Plaintiffs' motion to exclude their testimony should be denied.

Fred A. Mettler, Jr., M.D., M.P.H.

Dr. Mettler is a radiologist and nuclear medicine physician who holds a Master of Public Health. He has written hundreds of articles and twenty textbooks about radiation effects. (Mettler Decl. ¶ 1; Hr'g Day 2 at 160.) He has been the United States Representative to UNSCEAR for 29 years. (Hr'g Day 2 at 164.) He has also served in many capacities for the ICRP for several decades and he is an emeritus member of the NCRP. (Mettler Decl. ¶ 2; Hr'g Day 2 at 166.) He was involved in the original BEIR report in the 1970s and, as a member of the National Academy of Sciences nuclear and radiation studies board, he oversees BEIR's publications. (Hr'g Day 2 at 167.)

In his report, Dr. Mettler reviewed the literature to conclude that exposure to uranium had not been found to cause the cancers at issue in these cases, reviewed each person's probability of having contracted the particular cancer due to exposure to airborne uranium from the Apollo plant (which he found to be exceptionally low, ranging from zero to 0.3%, and for most of the plaintiffs less than 0.001% or less than one in 100,000) and criticized the claims made by Dr. Hu and Dr. Melius in their reports. (Mettler Decl. ¶¶ 9-10.) Dr. Mettler explained that government

[36] ECF No. 234 Exs. J, K.

compensation programs such as EEOICPA may cite scientific studies, but are often based on legislative and political concerns and do not support the proposition that a connection can be found between the substance and the cancer. (Hr'g Day 2 at 176, 189.)

Plaintiffs contend that Dr. Mettler's probability of causation analysis does not aid the trier of fact, that it relies upon unsupported and unreliable deviations from the model used by the federal government, and that it relies upon flawed source term and dose reconstruction performed by Dr. Till. Dr. Mettler's use of "but for" causation is wrong because the standard under Pennsylvania law is "substantial contributing factor" analysis. He uses 50% or more probability (a doubling dose) and makes several significant alterations to the model.

Defendants respond that the probability of causation technique was established decades ago and has been cited by Dr. Mettler in peer-reviewed publications including his own treatise on the health effects of radiation (a book cited heavily in Third Circuit cases, including 36 times in the TMI case) and it has never been rejected by any court. As Dr. Mettler explained, there is no basis for finding causation at such low doses as Plaintiffs likely received in these cases, but that fact does not mean that one cannot apply the probability of causation formula to this situation. They note that the plaintiffs in the Hall case made the same argument, but it was rejected and Dr. Mettler testified as an expert. Finally, they contend that Plaintiffs' contentions go to the weight of Dr. Mettler's testimony, not its admissibility and they present no argument concerning prejudice, thus providing no basis for a Rule 403 exclusion.

The NCRP first endorsed probability of causation in its Statement No. 7, where it recognized that because radiation is not generally known to leave a characteristic marker in cells it has transformed, "it is not possible, on the basis of medical evaluation, to unequivocally prove or disprove a claim that a specific malignancy was caused by a specified radiation exposure."

(ECF No. 239 Ex. B at 1.) Thus, the "primary basis" for assessing causation:

> must be human data on the excess frequency of malignancies following exposure to ionizing radiation, i.e., risk coefficients derived from epidemiological studies of populations exposed to ionizing radiation. The human data suitable for use in developing risk coefficients have been summarized in several reports, e.g., UNSCEAR (1988), NAS/NRC (1990) and NCRP (1992).

Id.

The NCRP has endorsed the probability of causation approach as "an epidemiology-based-method of developing an estimate of the probability, rather than proof, that, but for the specific radiation exposure, the specified malignancy would not have appeared." Id. at 1-2. The NCRP has found this approach to be a "reasonable way" to address the likelihood of radiation causation and "recommends that [it] be used as an aid in deciding the question of cause and effect between a malignancy and a specified previous exposure to ionizing radiation." Id. at 3.

Defendants note that, recently, the NCRP reaffirmed the probability of causation model as an effective tool for expressing the risk of a given cancer as a function of dose, gender, age at exposure and time since exposure. In its Report No. 171, the NCRP stated:

> Assigned share, probability of causation, and attributable risk are terms used, generally interchangeably, in determining the extent to which it is reasonable to infer that a cancer that is diagnosed in an individual with a given history of radiation exposure would not, in the absence of that exposure history, have occurred when it did and might therefore be attributed to that exposure history. In the absence of biological markers of radiation causation it is generally not possible to make such a determination with a high level of confidence since cancers may, and do, occur in the absence of exposure to a particular carcinogen of interest, including ionizing radiation, and, conversely, may and do fail to occur in the presence of exposure.

Id. Ex. C at 194.

In addition, the BEIR Committee of the National Academy of Sciences and National

Research Council, in its Report on Health Risk from Exposure to Low Levels of Ionizing Radiation (BEIR VII), describes the probability of causation formula and provides recommendations for application of the BEIR cancer risk estimates using the formula. (ECF No. 239 Ex. D at 265) ("The theory of risk assessment, modeling, and estimation and the computational software for deriving statistically sound parameter estimates from data provide a powerful set of tools for calculating risk estimates."). A combined publication by the WHO, International Atomic Energy Agency, and International Labour Organization similarly provides "guidance on the formulation and application of probability of causation schemes for the compensation of workers for radiation-induced occupational diseases." (Id. Ex. E at 2). The WHO recommends use of probability of causation to "identif[y] those cases of cancer that are most deserving of consideration of attributability" to radiation exposure. Id. at 11-12. See TMI, 193 F.3d at 727 (noting NCRP endorsement of probability of causation approach).

In their reply brief, Plaintiffs argue that Defendants have cited no case in which a court approved the probability of causation analysis, that Dr. Mettler has testified that he does not believe uranium was capable of causing cancer generally (thus, probability of causation is irrelevant) (Mettler Dep. at 84-85, 152),[37] that his methodology asks if radiation is the sole cause and therefore is unhelpful when multiple carcinogens are considered (Mettler Dep. at 105-06), that he has not identified the amount of uncertainty in the calculation (Mettler Dep. at 125), and that it is dependent upon the dose reconstruction and source term estimates provided by Dr. Till, which Plaintiffs have challenged.

At the hearing, Dr. Mettler testified that, contrary to popular opinion, radiation has not

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[37] Pls.' Reply Br. (ECF No. 256 Ex. A.)

been documented to contribute in a major way to the development of cancers (it is much weaker than chemicals, for example). (Hr'g Day 2 at 168, 174.) In fact, of the 86,000 survivors of the atomic bombs dropped on Hiroshima and Nagasaki (these individuals having been extensively studied), he noted that only 600-700 excess cancers have occurred (that is, above what would normally occur in the population). (Hr'g Day 2 at 168-69.) Moreover, different tissues in the body react differently, some being more susceptible to cancer than others, so that Dr. Hu and Dr. Melius committed a serious error in lumping together all of the 75 Plaintiffs, with various cancers. (Hr'g Day 2 at 170.)

Dr. Mettler stated that, below 10,000 millirems there is no linear relationship with cancer because the increase would be so statistically small and Dr. Melius erred in referring to a liner no-threshold model, which is used for protection purposes. (Hr'g Day 2 at 178.) He explained that the body suffers small radiation doses each day, from which it repairs itself—that is why, in using nuclear medicine (exposing patients to radioactive materials), Dr. Mettler spreads out nuclear therapy instead of applying it all at once. In the latest United Nations report, they used a linear quadratic relationship, not a linear no-threshold relationship. (Hr'g Day a 2 at 178-79.)

He testified that uranium radiation cannot go through a piece of paper, that if ingested it is often eliminated by the kidneys, that it has such a long half-life that a human being is exposed to very little radiation in a lifetime and that the process of enrichment (which increases the amount of U-235, which is 20% more radioactive that U-238) makes little difference in this analysis. (Hr'g Day 2 at 181-85.) He opined that, if someone offers a causation opinion and has available the vast amount of epidemiological research and data that went into UNSCEAR's findings and either failed to disclose it or review it, that would not be proper scientific methodology. (Hr'g Day 2 at 182.) In its most recent publication (February 2013), ATSDR

states that no health effects have been linked to uranium exposure other than damage to the kidneys from ingesting it. He also noted that it said nothing about enriched uranium and carcinogenicity, although it did say neither natural or depleted uranium has been classified with respect to it, and if there were a finding it would be there. (Hr'g Day 2 at 186-88.)

He explained that Americans experience an average background dose of natural radiation of about 300 millirems per year, to which he adds another 300 millirems from medical procedures (although this figure was only 50 millirems in 1980). (Hr'g Day 2 at 193-94.) See TMI, 193 F.3d at 644 n.50, 647 n.58. Dr. Mettler testified that he could not test Dr. Melius's opinion, but he was able to demonstrate its falsity. (Hr'g Day 2 at 197.) The probability of causation analysis has been around for a long time and has been endorsed by the International Labor Organization, the WHO and the International Atomic Agency. (Hr'g Day 2 at 198-99.) Dr. Mettler applied it here, excluded people whose cancers are known not to be caused by radiation (such as prostate and uterine cancer) and relied upon Dr. Till's calculation of dose to conclude that Plaintiffs received 1 millirem or less of radiation from the Apollo plant. (Hr'g Day 2 at 199-200.) The results were that the probabilities for Plaintiffs to contract cancer from uranium released at Apollo ranged from one-tenth of a percent to one in a million. (Hr'g Day 2 at 201.)

Plaintiffs have not demonstrated that Dr. Mettler's testimony should be excluded under Daubert. His testimony would aid the trier of fact. The probability of causation analysis he employed has been approved of by various scientific organizations and has never been excluded under Daubert. His reliance on data from Dr. Till does not alter the analysis, as the Court should conclude, for the reasons stated above, that Dr. Till's testimony should not be excluded. Plaintiffs' challenges would properly be the focus of cross-examination, but do not require the

exclusion of his testimony. Therefore, the motion to exclude Dr. Mettler's expert testimony should be denied.

John D. Boice, Jr., Sc.D. [38]

Dr. Boice is a professor of medicine with a Doctorate of Science in epidemiology. As noted by Dr. Mettler, Dr. Boice is the president of NCRP and is one of the world's top radiation epidemiologists. (Hr'g Day 2 at 167.) See Meier Decl. (ECF No. 242) Ex. A. Dr. Boice is not a retained expert of Defendants in these cases. Plaintiffs seek to prohibit Defendants from relying on studies that Dr. Boice conducted. Defendants had hired Dr. Boice in 2003 to defend against cancer claims arising out of alleged exposure to radioactive emissions from the plant and he updated PDH studies with new data and changed methodology.

Plaintiffs contend that Dr. Boice failed to disclose the litigation purposes of his studies or his retention as an expert, that he failed to perform a proximity analysis, that he destroyed the addresses and other location information for the reported cancer cases within the municipalities (the "Location Data") upon completion of his studies, that Defendants listed him in these cases as a "fact witness" but now are using him as an expert to avoid the requirement of Rule 26(a)(2)(C) that he submit a written report. They argue that his reports should be precluded under Rule 37(c) based upon spoliation. In addition, they contend that the Boice studies are hearsay not falling within the "learned treatise" exception of Rule 803(18) because they were published "with a view toward litigation." Finally, they argue that the studies are unhelpful because they combine data from Parks and Apollo, even though the Parks facility is now not part of the case.

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[38] Plaintiffs' challenge to Dr. Boice is based solely on the record; no testimony was presented by him at the hearing.

Defendants respond that Dr. Boice, although retained as an expert in the Hall case, was subsequently elected as president of the NCRP and cannot serve as a retained litigation expert and thus they properly disclosed him as a "non-retained" expert under Rule 26. In addition, he was deposed for a full day, so Plaintiffs had plenty of opportunity to question him. They respond that the argument about spoliation is a red herring. The PDH gave Dr. Boice private identifying information regarding each Plaintiff which he was not permitted to share with anyone. (Boice Dep. II at 69:16-70:4.)[39] In addition, to demonstrate spoliation, a party must show that: 1) the evidence was in the other party's control; 2) the evidence is relevant to the claims or defenses in the case; 3) there has been actual suppression or withholding of evidence; and 4) the duty to preserve the evidence was reasonably foreseeable to the other party. See Bull v. United Parcel Serv., Inc., 665 F.3d 68, 73 (3d Cir. 2012) (citation omitted). They contend that Plaintiffs have not met any of these factors. Here, Defendants preserved the back-up spreadsheets for Dr. Boice's studies and there was no other relevant data under his (or their) control. Even Dr. Hu, who criticizes Dr. Boice's studies for other reasons, does not claim that his address correction process was improperly conducted or that he needed any further data supporting the studies. (Hu Dep. at 205:19-206:14.)[40]

Defendants argue that epidemiological studies and other scientific literature are commonly relied upon by expert witnesses, as Dr. Hu did in referring to the Boice studies, regardless of whether the studies are "hearsay." Finally, they contend that there is no support for Plaintiffs' "litigation bias" argument—Dr. Boice testified that he designed the studies in 2000, seven years before Defendants' law firm became involved in litigation. (Boice Dep. I at 14:9-

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[39] ECF No. 242 Ex. B.
[40] ECF No. 242 Ex. L.

15:5.)[41]

In their reply brief, Plaintiffs note that Dr. Boice reclassified 377 of 935 cancer cases reported by PDH out of the study area, even though parts of the communities were proximate to the Apollo plant (which increases the risk of exposure), but he was unable to state how many of these people actually lived closer to the plant than the populations in the study area because he did not look. (Boice Dep. II at 17, 20-21, 25-26, 32, 35, 249-52, 260-62.)[42] Thus, they contend that his failure to preserve the location data prevents them from examining this crucial aspect of the studies. They further note that Atlantic Richfield knew very well about the importance of underlying data because it had litigated this very question in another case in which it was similarly represented by Arnold & Porter, LLP, its counsel herein. (ECF No. 259 Ex. D.) They argue that Defendants were aware from the Hall litigation that litigants were seeking this very information. (ECF No. 259 Ex. E.) And they contend that Dr. Boice did not check the boxes on the Applications for Access to Protected at Data indicating that the data should be preserved (ECF No. 259 Ex. F at 8 Ex. G at 7), and instead vaguely wrote in 2000 that "[o]ur intent is to publish our findings … in the scientific literature. Thus the findings may or may not be used in litigation, I imagine." (ECF No. 259 Ex. H.)

Plaintiffs have not demonstrated that the Boice studies should be excluded under Daubert. Contrary to Plaintiffs' contention, Dr. Boice is not a retained expert and he did not need to file a Rule 26 report. His studies, even if they constitute hearsay, may be referred to by other experts in these cases and Plaintiffs have cited no authority to the contrary. Finally, they have not demonstrated that he destroyed the evidence. Therefore, with respect to Dr. Boice, the

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[41] ECF No. 242 Ex. C.
[42] Rodes Decl. (ECF No. 259) Ex. B.

motion to exclude his studies under Daubert should be denied.

Donal Kirwan[43]

Kirwan is Plaintiffs' damages expert. Defendants contend that, although his report was due by October 30, 2012, he submitted only a proposed methodology and no plaintiff-specific information until January 11, 2013, the day before his deposition. They further note that even this data contained only partial damage calculations for only 28 of the 75 Plaintiffs. They contend that his report should be precluded as a sanction under Rules 37(b)(2)(A) and 16(f)(1) for violating the Court's scheduling order, resulting in prejudice to Defendants in limiting their ability to prepare a damages defense. In the alternative, they request that his report be precluded under Federal Rule of Evidence 702 because the Court cannot perform its gatekeeping function with the data Kirwan has provided.

Plaintiffs respond that Kirwan was contacted in September 2012 and he submitted his report on October 31, 2012. This report is not deficient simply because it did not include later-generated calculations as to each plaintiff: in fact, Defendants do not even argue that the report is insufficient. Kirwan can testify as to his method and allow the jury to apply it to the facts. In the alternative, even if his report is insufficient, excluding his testimony is a draconian measure and Defendants do not cite a single case that would support such a conclusion. Rule 26(a)(2)(B) does not limit an expert's testimony to his report; Kirwan could supplement it and be cross-examined about it. Defendants' motion could also be characterized as a premature motion in limine.

Defendants have not demonstrated that the severe penalty of exclusion should apply to

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[43] Defendants' challenge to Kirwan is based solely on the record; no testimony was presented by him at the hearing.

Kirwan because he did not submit his report in a timely manner. Rule 26(a)(2)(B) would allow him to supplement his report and he could be cross-examined about it. Therefore, the motion to exclude his testimony should be denied.

Result of Daubert Rulings

The most recent case management order indicates that Defendants have until August 5, 2013 to file motions for summary judgment in these cases, that Plaintiffs have until August 26, 2013 to respond and that Defendants may file reply briefs by September 6, 2013. However, a review of the case law indicates that, when the plaintiffs in a public liability action cannot present the testimony of their experts on causation to the trier of fact because of successful Daubert challenges, their case is at an end.

In TMI, the district court excluded almost all of the plaintiffs' experts pursuant to Daubert. The court then granted the defendants' motion for summary judgment. "The District Court's grant of summary judgment in favor of the defendants was the inevitable result of its exclusion of the testimony of the Trial Plaintiffs' dose exposure witnesses." 193 F.3d at 716. The Court of Appeals concluded that the district court abused its discretion in excluding a particular cancer study. Nevertheless, because that study was based on an assumption of high levels of radiation exposure that the plaintiffs were unable to prove, its inclusion did not alter the result and the court affirmed the order granting summary judgment. Id. at 716-17. See also Cano, 362 F. Supp. 2d at 816 ("Because Dr. Dollinger's testimony is the Plaintiffs' sole evidence regarding specific causation, the Court also GRANTS Defendants' Motion for Summary Judgment Based Upon Plaintiffs' Lack of Admissible Proof and DISMISSES this case WITH PREJUDICE.")

For all of the reasons identified above, the motions to exclude Plaintiffs' expert on

general causation (Dr. Hu) and Plaintiffs' expert on specific causation (Dr. Melius) should be granted. Therefore, it is recommended that, if the Court adopts this Report and Recommendation, Plaintiffs be given 21 days from the date of the order to show cause why summary judgment should not be entered in Defendants' favor.

For these reasons, it is recommended that Defendants' Motion to Exclude Expert Opinions of Mr. Bernd Franke and Joseph Ring, Ph.D., under *Daubert* be granted. It is further recommended that Defendants' Motion to Exclude Expert Testimony and Opinions of Donal Kirwan be denied. It is further recommended that Defendants' Motion to Exclude Expert Opinions of Howard Hu under *Daubert* be granted. It is further recommended that Defendants' Motion to Exclude Testimony of James Melius under *Daubert* be granted. It is further recommended that Plaintiffs' Motion to Exclude the Opinions of Defendant Babcock & Wilcox's Retained Expert John E. Till Ph.D. be denied. It is further recommended that Plaintiffs' Motion to Exclude the Opinions of Defendant Babcock & Wilcox's Retained Experts Dr. Christopher Whipple and Stanley Hayes be denied. It is further recommended that Plaintiffs' Motion to Exclude Testimony and Report of Fred A. Mettler, Jr., M.D., M.P.H. be denied. It is further recommended that Plaintiffs' Motion to Exclude Testimony and Studies of Dr. Boice be denied. It is further recommended that Plaintiffs' Motion to Exclude Testimony and Studies of Dr. Boice be denied. It is further recommended that, if the Court adopts this Report and Recommendation, Plaintiffs be given 21 days from the date of the order to show cause why summary judgment should not be entered in Defendants' favor for the reasons stated herein.

Litigants who seek to challenge this Report and Recommendation must seek review by the district judge by filing objections by July 26, 2013. Any party opposing the objections shall file a response by August 9, 2013. Failure to file timely objections will waive the right of

appeal.

s/Robert C. Mitchell
ROBERT C. MITCHELL
UNITED STATES MAGISTRATE JUDGE

Dated: July 12, 2013